In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: May 25, 2022

JAMES LAGLE,	*	Published
Petitioner,	*	
	*	No. 16-1053V
v.	*	
	*	Special Master Gowen
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Ruling on Entitlement; Intradermal Influenza ("flu") Vaccine; Shoulder Pain and Dysfunction.
Respondent.	*	

Leah V. Durant, Law Offices of Leah V. Durant, PLLC, Washington, D.C., for petitioner.
Christine M. Becer, U.S. Department of Justice, Washington, D.C., for respondent.

RULING ON ENTITLEMENT[1]

On August 25, 2016, James Lagle ("petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program.[2] Petitioner alleges that as a result of receiving an influenza ("flu") vaccine administered intradermally in his right arm he suffered shoulder pain and dysfunction. Petition (ECF No. 1). After a review of the record and an entitlement hearing, petitioner has established by preponderant evidence that he is entitled to compensation.

I. Procedural History

Petitioner filed his claim for compensation on August 25, 2016. Petition. Petitioner alleged that as a result of receiving the flu vaccination in his right arm on October 20, 2015, he suffered

[1] Pursuant to the E-Government Act of 2002, see 44 U.S.C. § 3501 note (2012), **because this opinion contains a reasoned explanation for the action in this case, I intend to post it on the website of the United States Court of Federal Claims.** The Court's website is at http://www.uscfc.uscourts.gov/aggregator/sources/7. Before the opinion is posted on the Court's website, each party has 14 days to file a motion requesting redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). An objecting party must provide the Court with a proposed redacted version of the opinion. *Id.* **If neither party files a motion for redaction within 14 days, the opinion will be posted on the Court's website without any changes.** *Id.*

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to 34 (2012) (hereinafter "Vaccine Act" or "the Act"). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

a "Shoulder Injury Related to Vaccine Administration ("SIRVA")." *Id.* at Preamble. The case was assigned to the Special Processing Unit ("SPU"), with former Chief Special Master Dorsey as the presiding Special Master. *See* SPU Initial Order (ECF No. 4).

On November 30, 2016, respondent filed the Rule 4(c) report recommending that compensation be denied. Respondent's ("Resp.") Report ("Rept.") at 1 (ECF No. 10). Respondent noted that the flu vaccine petitioner received on October 20, 2015, was administered intradermally and not intramuscularly and therefore he is not eligible for a Table SIRVA. *Id.* at 5. Respondent asserted that petitioner must provide a medical theory for how a vaccine administered intradermally could cause a right shoulder injury. *Id.* Further, respondent asserted that petitioner did not seek medical attention for his right shoulder pain or dysfunction for three months post-vaccination and therefore, could not establish a proximate temporal relationship between vaccination and injury. *Id.*

The case was reassigned to my docket on December 1, 2016. Notice of Reassignment (ECF No. 13). I held a status conference on January 12, 2017 and ordered petitioner to file an expert report and additional medical literature. Scheduling Order (ECF No. 14). On June 1, 2017, petitioner filed an expert report written by Catherine Shaer, MD.[3] Petitioner's ("Pet.") Exhibit ("Ex.") 14. Dr. Shaer stated, "I do not believe that the only mechanism of injury in SIRVA cases is that an improperly administered vaccine enters the sub-deltoid bursa and causes an inflammatory bursitis." Pet. Ex. 14 at 2. She also stated, "Although the current Vaccine Injury Table specifies that vaccines must be given IM ("intramuscularly") to qualify as a Table [injury], it is clear that improperly administered ID ("intradermally") vaccines can be injected into tissues that were not meant to receive the antigen and can cause an inflammatory reaction." *Id.*

Respondent filed a responsive expert report written by Harry W. Schroeder, Jr., MD.[4] Resp. Ex. A (ECF No. 25). Dr. Schroeder wrote that intradermal vaccines are injected into the skin using a microneedle that penetrates 1.5 mm into the skin using a pre-filled, ready to use syringe. Resp. Ex. A at 8. He also wrote, "The length of the needle used for Fluzone is simply

[3] Dr. Catherine Shaer received her undergraduate degree from Quinnipiac University in 1974 and received her medical degree from the University of Texas Health Science center in 1978. Pet. Ex. 14 at 1; Pet. Ex. 15 at 1. She completed her residency at Children's Hospital National Medical Center in 1981. *Id.* Dr. Shaer was board certified in pediatrics in 1984. Dr. Shaer is currently licensed to practice medicine in the state of Maryland. Pet. Ex. 15. From 1982 to 1999, Dr. Shaer worked as a medical director at Children's National Medical Center in Washington, D.C. *Id.* at 3. From 2008-2014, Dr. Shaer worked as a medical officer at the Division of Vaccine Injury Compensation at the Department of Health and Human Services. *Id.* at 2. She was promoted to Branch Chief at the Division of Vaccine Injury Compensation in 2011 and ultimately left the Department of Health and Human Services in 2014. *Id.* at 1. Dr. Shaer has co-authored numerous medical articles related to childhood spina bifida. *Id.* at 5-8.

[4] Dr. Schroeder is currently a professor of medicine, microbiology and genetics at the School of Medicine at the University of Alabama ("UAB"). Resp. Ex. A at 1. Dr. Schroeder received his undergraduate degree from Texas A&M in 1974 and his medical degree from Baylor College of Medicine in 1981. Resp. Ex. B at 2. Additionally, he received his PhD in cell biology in 1979. *Id.* Dr. Schroeder did his residency at the University of Kentucky Medical Center from 1982-1984. *Id.* He has been teaching at the University of Alabama since July 1988. *Id.* Additionally, Dr. Schroeder is the editor of the textbook *Clinical Immunology: Principles and Practices*, and he has conducted clinical practice at UAB evaluating patients with immune mediated diseases. Resp. Ex. A at 1. Finally, Dr. Schroeder is active in academic research. Resp. Ex. B at 11-15. Dr. Schroeder was admitted as an expert in immunology during the hearing. Tr. 170-71.

too small to reach the tissues that were injured in the petitioner." *Id.* at 9. Dr. Schroeder wrote, "I believe, to a degree of reasonable medical probability, that [petitioner] developed shoulder pain from rotator cuff tears early in the month of November 2015…I do not believe that the pain that appeared in November 2015, nor the tears that were first documented in March of 2016 were caused by the Fluzone vaccine he received on October 20, 2015." *Id.*

I held a Rule 5 status conference on October 19, 2017. Rule 5 Order (ECF No. 27). During the status conference, I stated that if Dr. Shaer's measurements were accurate it "would suggest that an intradermal needle can reach the underlying structures in the shoulder if improperly administered." *Id.* at 1. I also noted that the onset of petitioner's pain appeared to remain an issue. *Id.* at 1-2. I ordered petitioner to file additional affidavits from individuals familiar with his injury and had knowledge relating to the onset of his symptoms and that petitioner may file a supplemental report regarding the Fluzone needle length. *Id.*

On October 20, 2017, respondent filed the Fluzone Fact Sheet. Resp. Ex. H (ECF No. 28). Petitioner filed a supplemental report from Dr. Shaer on November 20, 2017. Pet. Ex. 17. On March 1, 2018, I held another status conference, reviewing petitioner's supplemental expert report. Order (ECF No. 39). I agreed with Dr. Schroeder that it seems unlikely that the vaccine caused petitioner's full rotator cuff tear but questioned why petitioner's rotator cuff tear would suddenly become painful post-vaccination. *Id.* at 2. In this order, I asked a series of questions directed to petitioner's expert to answer. *Id.*

On April 30, 2018, petitioner filed an expert report from Marko Bodor, MD.[5] Pet. Ex. 18 (ECF No. 40). Respondent filed a supplemental report from Paul Cagle, MD.[6] Resp. Ex. J (ECF No. 42). I held a third status conference in this case on September 6, 2018. Scheduling Order (ECF No. 47). During this status conference, I reviewed the additional expert reports filed by both parties and explained that "petitioner has a reasonable possibility of recovery in this case." *Id.* at 2. I recommended the parties seek to settle the case based on litigative risk. *Id.*

[5] Dr. Marko Bodor is a Doctor of Physical Medicine and Rehabilitation, with sub-specialties in pain management and sports management. Pet. Ex. 19 (ECF No. 40). He received his undergraduate degree from Harvard College in 1982 and received his medical degree from the University of Cincinnati Medical School in 1987. *Id.* at 1. Dr. Bodor is licensed in the state of California, and he is board certified in neuromuscular and electrodiagnostic medicine. *Id.* at 1. He previously held positions as an emergency physician and attending physiatrist from 1988 through 1994. *Id.* Since 1995, he has practiced as an interventional physiatrist in private practice. *Id.* at 2. Additionally, Dr. Bodor serves a voluntary assistant professor at the Department of Neurological Surgery at the University of California San Francisco. *Id.* at 1. Dr. Bodor continues to treat approximately thirty patients per day. *Id.* at 2. Additionally, Dr. Bodor has written and co-authored numerous peer-reviewed medical articles, including the article, *Vaccination related shoulder dysfunction,* which the respondent cited when proposing to add SIRVA to the Vaccine Injury Table. Dr. Bodor was admitted as an expert in physical medicine, sports medicine, pain medicine, electromyography, diagnostic ultrasound, and a spine specialist. Tr. 133.

[6] Dr. Paul Cagle is an orthopaedic surgeon who serves as an Assistant Professor and Associate Program Director in the Department of Orthopaedic Surgery at the Icahn School of Medicine at Mount Sinai. Resp. Ex. K; Tr. 222. Dr. Cagle received his medical degree from the Loyola University Chicago Stritch School of Medicine. *Id.* He did a residency in orthopaedic surgery at the University of Minnesota Academic Health Center and Medical School from 2008-2013. *Id.* He board certified in orthopaedic surgery. *Id.*; Tr. 223. Prior to working at Mount Sinai, Dr. Cagle was an assistant professor and interim chair of the Department of Orthopaedic Surgery at Southern Illinois University School of Medicine. *Id.* He has published numerous articles in peer reviewed journals. *Id.* at 3-14. Dr. Cagle was admitted as an expert in orthopedic surgery. Tr. 225.

After unfruitful settlement negotiations, the parties requested that an entitlement hearing be set. Joint Status Rept. (ECF No. 54). Both parties filed pre-hearing submissions and petitioner filed another expert report from Uma Srikumaran, MD.[7] Pet. Ex. 25 (ECF No. 61).

An entitlement hearing was held on February 23-24, 2021. Following the hearing both parties filed post-hearing briefs. Pet. Post Hearing Brief (ECF No. 73) & Resp. Post-Hearing Brief ("Resp. Brief") (ECF No. 75). Petitioner filed a reply to respondent's post-hearing brief on July 6, 2021. Pet. Reply (ECF No. 76).

This matter is now ripe for adjudication.

II. Petitioner's Medical History

a. Medical Records

At an appointment with his primary care physician ("PCP") on September 28, 2015, petitioner reported that he was experiencing some gastrointestinal issues. Pet. Ex. 2 at 135. It was noted that he was thin, but not ill appearing, his lungs were clear, his cardiac rhythm was regular, and he had no edema in the lower extremities. *Id.*

On October 20, 2015, petitioner, who was 59 years-old at the time, received the flu vaccine administered to his right deltoid. Pet. Ex. 1 at 1. The vaccination record indicates that the administration route was "intradermal." *Id.*

On November 10, 2015, petitioner had an "acute visit" with his primary care physician, Dr. Keith Sutton. Pet. Ex. 2 at 137. The reason for the "acute visit" was for elevated blood pressure that was in the 190/180s at home. *Id.* Petitioner also reported increased fatigue and he was experiencing increased abdominal pain. *Id.* It was recorded that petitioner had "persistent elevation of blood pressure and some low-grade headache." *Id.* Dr. Sutton diagnosed petitioner with essential hypertension and increased petitioner's daily dose of Lisinopril and prescribed hydrochlorothiazide daily. *Id.*

Petitioner returned to Dr. Sutton on January 6, 2016, for re-check of his hypertension and to determine if the dosing of Lisinopril was appropriate. *Id.* at 138. Petitioner explained that he was feeling well and did not have any significant orthostatic hypotension. *Id.* His blood

[7] Dr. Umasuthan ("Uma') Srikumaran is currently an associate professor in the Department of Orthopaedic Surgery at Johns Hopkins University School of Medicine. Pet. Ex. 26 (ECF No. 61). He received his undergraduate degree from Northwestern University College in 2001 and received his medical degree from Johns Hopkins University School of Medicine in 2005. *Id.* at 1. His residency was in Orthopaedic Surgery at Johns Hopkins University and he participated in a Fellowship in Shoulder Surgery at Massachusetts General Hospital and Brigham and Women's Hospital in Boston, MA. *Id.* In addition to his position at Johns Hopkins University School of Medicine in Baltimore, MD, Dr. Srikumaran is the department Chair of the Orthopaedic Surgery at Howard County General Hospital. *Id.* Dr. Srikumaran has been the lead author or co-author of numerous orthopedic related medical articles. *Id.* at 2-4. Additionally, his clinical focus is shoulder disorders involving traumatic injuries and degenerative conditions. *Id.* at 9. He is licensed to practice medicine in Maryland and is Board Certified by the American Board of Orthopaedic Surgery. *Id.* at 10.

pressure was taken in his left arm at this appointment. *Id.* Dr. Sutton wrote that petitioner was "thin, rather healthy-appearing, no acute distress." *Id.* at 139.

On January 12, 2016, petitioner's fiancé, Ms. Lori Beatty, called Dr. Sutton's office and the call note provides, "[petitioner] was given the flu shot in October and [petitioner] still has a mark where the injection was given, in addition he is experiencing numbness in finger and shoulder pain." Pet. Ex. 7 at 10. Further, the note indicates that Ms. Beatty stated that she thought it was from the injection. *Id.* The internal records show that the message was forwarded to Dr. Fawzla Haque in Dr. Sutton's office who wrote, "I am not sure, wait few days, apply heat on shoulder, Tylenol. If it bothers after several days, talk to your doctor." *Id.* Later that afternoon, Ms. Raylene Peters, from Dr. Sutton's office, called petitioner and recommended that he apply heat, take Tylenol for a few days and if it did not get better, to call Dr. Sutton. *Id.*

Eight days after the phone call, petitioner had an appointment with Dr. Sutton on January 20, 2016. The Nurse's Note states, "Acute appt today for pain in right shoulder since flu shot 10/2015. [Patient] states this began about two weeks after intradermal injection. No known injury to shoulder-[patient] states difficulty moving shoulder and arm…[patient] states he did call and was told to use warm compresses and Tylenol on 1/12/2016." Pet. Ex. 2 at 141. The "History of Present Illness" from this appointment provides, "Patient has pain with active abduction of the right shoulder localized to the posterior portion of the rotator cuff. He did have a flu shot several weeks ago, but that is not inflamed, does not remember any acute injury." *Id.* Dr. Sutton performed a targeted examination of petitioner's right shoulder and petitioner demonstrated increased pain with both active and passive abduction, and he was unable to abduct beyond 70 degrees without considerable discomfort. *Id.* Further, Dr. Sutton noted that "there is a trigger point over the posterior right rotator cuff in the subacromial space." *Id.* Petitioner received a steroid injection into his right shoulder. *Id.* Dr. Sutton diagnosed petitioner with bursitis of the right shoulder. *Id.* at 142.

Petitioner called Dr. Sutton's office on January 27, 2016 and explained that the cortisone shot did not improve his pain and asked for a referral to an orthopedist. Pet. Ex. 7 at 8. On February 4, 2016, petitioner appeared for an initial evaluation at Drayer Physical Therapy. Pet. Ex. 3 at 20. He was evaluated by physical therapist Lauren Leonard, PT. *Id.* At this appointment, petitioner reported that he "started getting pain in early November 2015 without MOI (mechanism of injury)." *Id.* It was noted that he could not "account for any injury or activity that brought on the pain." *Id.* Petitioner stated that he got a flu shot in October and "feels like it contributed to his symptoms." *Id.* The record also indicates that petitioner did not have any history of shoulder pain. *Id.*

Petitioner reported that his pain was in "the lateral deltoid" and that "at times it radiates down [to] forearm into lateral two fingers." *Id.* He described his pain at "best" as a 6 out of 10 and at its "worst" a 9 out of 10. *Id.* An examination of his right shoulder revealed impaired flexion and abduction for both passive and active range of motion. *Id.* PT Leonard noted passive abduction of his right shoulder "resulted in paresthesia in ulnar nerve distribution." *Id.* at 21. Petitioner's had moderate tenderness on his supraspinatus and rotator cuff. *Id.* at 22. He was able to internally rotate his right arm to L5 and was unable to externally rotate his right shoulder. *Id.* PT Leonard assessed with "ongoing shoulder pain without mechanism of injury

and she noted that petitioner "display[ed] signs of reduced capsular mobility in right shoulder along with impaired RTC function and function of scapular stabilizers." *Id.* at 23. She opined that he would benefit from skilled physical therapy and that his rehabilitation potential was good. *Id.*

Petitioner began physical therapy three times a week beginning on February 9, 2016. Pet. Ex. 3 at 18. His treatment diagnosis was, "Sprain of right rotator cuff capsule." *Id.* On February 12, 2016, petitioner was seen by Physical Therapist Assistant, Caitlin Myers and PT Leonard. *Id.* at 12. Petitioner reported that his pain had been increasing and he was very limited in his ability to perform tasks. *Id.* It was noted that petitioner was unable to sleep through the night due to pain, he had difficulty reaching for the steering wheel in his car, and that he had pain when trying to pull a shirt over his head. *Id.* at 13.

On February 16, 2016, petitioner had another physical therapy appointment with PT Leonard. *Id.* at 3. Petitioner reported that he had not seen an improvement in his symptoms and that he was still experiencing soreness in his shoulder when reaching away from his body. *Id.* He also reported that when he reaches overhead, he has a stabbing pain in the lateral portion of his shoulder. *Id.* Under "Assessment," PT Leonard wrote, "Patient has poor tolerance to treatment progression with increased resistance during manual PT. Patient continues to display symptoms of active inflammation combined with capsular tightness, which is resulting in self limiting active range of motion due to pain." *Id.* at 7. She recommended that petitioner continue physical therapy to increase active range of motion. *Id.*

On February 18, 2016, petitioner was discharged from physical therapy. *Id.* at 5. Petitioner reported that he was going to see an orthopedic surgeon and after that, may return to physical therapy. *Id.* During the exam of his right shoulder, petitioner demonstrated an increase in active flexion from 80 degrees to 125 degrees, but it was "painful." *Id.* at 2. He also had an increase in his active abduction, from 85 degrees to 110 degrees, but it was also "painful." *Id.*

Petitioner had an X-ray of his right shoulder on March 15, 2016. Pet. Ex. 2 at 361. Under "Indication," it stated, "Pain, right shoulder, post flu shot in October 2015, no known injury." *Id.* The x-ray showed mild degenerative changes in the acromioclavicular joint. *Id.* The same day, petitioner saw orthopedist Dr. William Demuth. *Id.* at 143. Under "History of Present Illness," petitioner reported that he was having pain in his right shoulder for "a number of months," and petitioner related "that in the general timeframe to a flu shot." *Id.* Dr. Demuth noted that he "doubt[ed] that [the flu shot] has anything to do with this." *Id.* Dr. Demuth also wrote that petitioner's arm was "weak" and "has difficulty consistent with a rotator cuff tear." *Id.* The physical demonstrated that petitioner had significant discomfort on internal and external rotation and he had pain in the subacromial space when trying to elevate his arm above 90 degrees. *Id.* Dr. Demuth diagnosed petitioner with "bursitis of the right shoulder," and recommended petitioner have an MRI of his right shoulder. *Id.*

The next day, March 16, 2016, petitioner had an MRI of his right shoulder. Pet. Ex. 2 at 365. The MRI showed mild increased T1 and T2 signal within the supraspinatus and infraspinatus tendon; focal fluid signal intensity on the anterior aspect of the supraspinatus tendon "compatible with a focal high-grade tear involving 70% cross sectional fibers; and

moderate generalized thinning of the superior half of the subscapularis tendon with a partial tear. *Id.* The interpretation of the MRI was "insertional high-grade partial tear, moderate partial tear superior fibers subscapularis tendon, moderate AC joint degenerative changes, mild bursitis and mild partial tearing intra-articular of the biceps tendon." *Id.*

On March 22, 2016, petitioner had a follow-up appointment with Dr. Demuth. Pet. Ex. 2 at 148-49. Dr. Demuth stated that petitioner's "MRI demonstrates a rotator cuff tear. He is having pain with range of motion and use of the right arm." *Id.* at 148. After a physical exam, which showed petitioner had "difficulty with both abduction and flexion of his right arm, as well as, internal and external rotation." Dr. Demuth diagnosed petitioner with "complete rotator cuff tear or rupture of right shoulder." *Id.* at 149. Dr. Demuth recommended a rotator cuff repair because petitioner was not getting any significant relief with injections. *Id.*

Petitioner presented to Blair Memorial Hospital on May 17, 2016 for a "right shoulder rotator cuff repair with acromioplasty." Pet. Ex. 2 at 382. On the operative report under the "Indication" section, it was noted that petitioner had a diagnostic workup, including an MRI which showed, "a rotator cuff tear, full thickness, with impingement." *Id.* During the operation a "full thickness rotator cuff tear directly in the supraspinatus area was identified." *Id.*

Petitioner had a post-operative appointment on May 31, 2016 with Dr. Demuth. Pet. Ex. 2 at 384. Dr. Demuth noted that petitioner was "doing well," and that he would start exercises soon. *Id.*

On October 4, 2016, petitioner returned to Dr. Demuth for a four-month post-operative appointment. Pet. Ex. 6 at 1. During this appointment, petitioner reported "no major pain in his right shoulder," and indicated that he was doing "his regular job at work." *Id.* A physical exam revealed that petitioner could elevate both arms above his head and his reflexes were symmetric in the upper extremities. *Id.* Dr. Demuth recommended that petitioner be allowed to do his regular job at work and that petitioner perform home exercises. *Id.*

Between November 2016 and 2021, petitioner's medical appointments mostly focused on treating other medical conditions unrelated to his shoulder. On February 9, 2021, petitioner had an appointment with Dr. Philip Bosha. Pet. Ex. 36 at 1. At this appointment, it was noted that petitioner was referred for an ultrasound of his right shoulder "secondary to a history of chronic right shoulder pain after a[n] influenza vaccine injection in 2015." *Id.* Under the HPI, it noted that petitioner previously had surgery in 2016 and he was now experiencing paresthesia in his right arm. *Id.* The ultrasound evaluation focused on the subacromial and lateral aspects of petitioner's right shoulder. *Id.* Dr. Bosha noted that petitioner had degenerative and tendinopathic changes of the supraspinatus tendon and there was decreased subacromial space. *Id.* Petitioner's skin thickness of this area measured between 2 mm to 4 mm. *Id.* at 2. Dr. Bosha also evaluated the infraspinatus and teres minor tendon. He observed degenerative and tendinopathic changes of the infraspinatus tendon and skin thickness again ranged between 2 mm to 4 mm. *Id.* Dr. Bosha diagnosed petitioner with right shoulder pain and instructed to follow-up with his orthopedic surgeon as needed. *Id.* at 2.

b. Hearing Testimony

1. Testimony of Petitioner

During the hearing held on February 23, 2021, petitioner testified that on October 20, 2015, he went to his doctor's office and received a flu vaccine. Transcript ("Tr.") at 6. He stated that, "Then I went home, and it wasn't within hours, it just seemed to be too sore for the injection." *Id.* Petitioner explained that after he left Dr. Sutton's office, he went to have lunch with his mother and sisters. *Id.* at 7. He testified that he had lunch with his family four or five days a week. *Id.* Petitioner stated that he told his sisters and mother during lunch that his arm was awfully sore for some reason. *Id.* He explained that he told his mother and sisters about the soreness in his arm because "it was worse than what it should have been." Tr. 18. Petitioner stated during the lunches with his family he would explain that his shoulder was getting worse. *Id.* at 35.

The Court ask petitioner to recall his appointment where he received the flu vaccination. Tr. 14. Petitioner explained that he was sitting down when he received the injection and that he had rolled his sleeve up to receive the shot. *Id.* He recalled that the medical assistant administering the shot was standing. *Id.* at 15. Petitioner testified that the injection was "given high on the right shoulder." *Id.* Petitioner stated that he had developed a red mark high on his right shoulder at the site of injection that took a long time to heal. *Id.* at 16.

Petitioner testified that approximately two or three days after he received the vaccine, he called Dr. Sutton's office and talked to a receptionist about the pain in his shoulder. Tr. 9. He stated that "someone from [Dr. Sutton's] office" called him and told him to take Tylenol for two to three weeks and get back to them. *Id.* Petitioner testified that he called back two to three weeks later, as instructed and told the receptionist that his shoulder was not getting better, but worse. *Id.*

He explained that the pain started two days after the vaccination and "kept getting worse and worse and worse." Tr. 14. He stated that he would talk about the pain in his shoulder "roughly every day, because it was getting worse." *Id.* at 13. When asked if his pain started hours after the vaccination, as he previously testified, or days later, petitioner stated, "Well, the one was just a soreness. The pain started like two days afterward. Yes. And then it just kept getting worse and worse and worse." Tr. 14. Later, petitioner testified, "…when I first received the injection, of course, it was sore like a regular injection, and then a couple of days after, it was just-the pain got worse then. It went from one to the other real quick." Tr. 33. Petitioner described the initial soreness as a "burning, tingling sensation," which began "right away." *Id.* at 34.

Petitioner testified that the January 6, 2016, appointment with Dr. Sutton, was for "a routine re-check" of his blood pressure. Tr. 11. Petitioner stated that he would get his blood pressure checked "once every month," or every two months. *Id.* He explained that during these visits he would "go in and she (Dr. Allison Holmes) just examines me and asks me if I'm having any problems or if I need medication renewed." *Id.* He clarified that during these visits he would see Dr. Sutton, but the appointments would last less than five minutes. *Id.* at 13. During

cross-examination, petitioner was asked if he had mentioned his right shoulder pain during the November 10, 2015 appointment, where he had his blood pressure checked Tr. 38; Pet. Ex. 2 at 136. Petitioner testified that Dr. Sutton already had known about his right shoulder pain, so he did not bring it up at this appointment. *Id.*

Petitioner was asked to recall his January 20, 2016 appointment with Dr. Sutton. Tr. 16. Petitioner testified that the nurse's note which recorded that petitioner's pain began two weeks after the injection, was an error. Tr. 17, 37. Petitioner stated that he remembered the visit, "but it wasn't the two weeks that had passed." *Id.* Petitioner reiterated that immediately after he received the vaccine his shoulder was sore, but the "pain gradually [came] on." *Id.* at 18. Petitioner explained that he told Dr. Sutton that his pain started right after the flu injection and that Dr. Sutton told him that the vaccination would not have caused the pain. *Id.* at 19. Petitioner stated that Dr. Sutton gave him a cortisone injection into the back area of his shoulder. *Id.* at 20.

When petitioner had his physical therapy evaluation on February 4, 2016, he told the physical therapist, "about the shoulder pain," and "that it was hurting." Tr. 25. When asked about the notation in the medical record which indication petitioner's pain began in "early November 2015," petitioner explained that "the pain was continuous…from October 20 to early November 2015." Tr. 25. He testified that the pain and soreness in his right shoulder was, "extremely worse in November." *Id.* at 26. Petitioner testified that time of the soreness until the pain had begun was a continuous period. *Id.* at. 26.

Petitioner testified that prior to undergoing his rotator cuff surgery, his pain was at a 10 out of 10 on the pain scale. Tr. 28. He stated that he was at this level of pain for about two months. *Id.* After his surgery, petitioner stated that his pain level "got extremely better" and dropped to a 3 or 4 out of 10. *Id.* He testified that he currently takes approximately 500 milligrams of Tylenol daily. *Id.* at 29. Petitioner also explained that his sleep is disrupted by muscle aches, numbness and tingling down his right arm at night. Tr. 32.

2. Testimony of Ms. Lori D. Beatty

Ms. Beatty, petitioner's fiancée, explained that they had been together for 20 years and lived together for 19 years. Tr. 41. She testified that she remembered the day he got the vaccination and later in the afternoon he was "already complaining that it seemed pretty sore…where he got the vaccine." *Id.* at 41-42. She stated, "later in…the evening….it was bothering him the same day he received it, but it got progressively worse." Tr. 45. Ms. Beatty stated that petitioner also complained about his arm being sore the next day and then "within the next couple of days…He said it was getting pretty painful." *Id.* at 42.

Later, Ms. Beatty testified that she had seen a mark on petitioner's right shoulder where he received the vaccination. *Id.* at 46. She described the vaccination site as, "the upper part of his shoulder, pretty high up on his shoulder." *Id.* She testified that the mark on petitioner's shoulder was a "reddish color," and "not a bruise." *Id.* at 46. She also testified that the mark was "[r]oughly the size of a nickel." *Id.* at 47. When the Court asked her to demonstrate where

the red mark was in relation to the end of her acromion, Ms. Beatty replied that the mark was, "Just maybe right below it." Tr. 47.

Ms. Beatty testified that petitioner would complain about his right shoulder pain a couple of times a day. Tr. 42. She stated that petitioner called the doctor's office a couple of days after he received the shot to inform the doctor of his pain. *Id.* Someone from Dr. Sutton's office "left a message at our home and stated that [petitioner] should just take Tylenol for the pain." *Id.* at 43. When asked if she remembered when petitioner called the doctor's office, she testified that she did not know the specific day, but that "it was definitely the same week that he received it." *Id.* Ms. Beatty stated that she had heard the voice message from the doctor's office and that it was a woman who left the message. *Id.* When asked to recall the content of the message, Ms. Beatty testified that the message said, "That they had received his call regarding the soreness and that he should take Tylenol for pain." *Id.* at 44.

Ms. Beatty also testified that she made calls to set up doctor's appointments for the petitioner. Tr. 45. When asked if she had any independent recollection of making the call to Dr. Sutton's office, she testified, "I'm sure I did…like I said, I make many phone calls for him, so I don't doubt that did I that." *Id.* at 46. During cross-examination, she also testified that she did not recall making any other phone calls to Dr. Sutton's office on behalf of petitioner between November and December 2015. *Id.* at 54.

Ms. Beatty explained that she and the petitioner would have lunch with his mother and three sisters almost every weekday during the lunch hour. *Id.* at 44. She also testified that during those lunches after the vaccination petitioner "would mention to his sisters and mother about the pain that he was having and stating that he never had the pain until after he received the flu shot." *Id.* at 44. Ms. Beatty stated that she and the petitioner went to his mother's house for lunch after he had received his flu shot. *Id.* at 51. She recalled him mentioning "that his arm seemed …sorer than you would expect from receiving a flu shot." *Id.* She testified that they had lunch with his family again the following day and petitioner mentioned that "he had soreness in his arm from where he got the flu shot, at the site of where he got the shot." *Id.* She further explained that she remembers the petitioner showing his sisters and mother his arm within a couple of days. *Id.* When asked how often petitioner brought up his shoulder during the lunches with his family, Ms. Beatty replied, "Probably every day, because it really bothered him. Or they would ask, 'How's your shoulder today?' " *Id.* at 52. She stated that, "It was pretty obvious that [his shoulder] was sore." *Id.*

When asked about how the petitioner was treating the pain in his shoulder, Ms. Beatty replied that he would take Tylenol and use a warm compress. Tr. 49. She explained that even physical therapy caused petitioner shoulder pain and the cortisone shot did not help petitioner's pain either. Tr. 48. She testified that petitioner had severe pain between the time he received the shot and his surgery. *Id.*

Ms. Beatty stated that petitioner's right shoulder injury made it difficult for him to engage in his hobbies, such as fishing or shooting. *Id.* at 49. She explained that he can sit in the boat, but is unable to cast out as he previously had done. *Id.* Ms. Beatty stated that petitioner has some minor discomfort, but that "It's a lot better than it was." *Id.* at 50.

3. Testimony of Ms. Shirley Prough

Ms. Shirley Prough, petitioner's sister, testified that she and her family members would meet every day for lunch. Tr. 57. She explained that she would attend the family lunch at least three to four days a week in October 2015. *Id.* Ms. Prough testified that she was 99 percent sure she had attended lunch the day petitioner received his flu shot. *Id.* at 56. She recalled that petitioner came to lunch after he received his flu shot and he complained about his arm being sore. *Id.* Ms. Prough also stated that every time she attended the lunch after the vaccination, she recalled petitioner complaining about his arm. *Id.* at 57. She testified, "While I was around him that lunch period, it was, you, the same. And then the next day or two later is when he said about how bad his arm hurt, he couldn't move it." *Id.* at 57.

She testified that petitioner's shoulder pain was "constantly there," and that, "We could basically know just by looking at him that he was in pain." Tr. 58. She also stated that petitioner always related the pain to his flu shot. *Id.* Ms. Prough testified that she never saw the location on petitioner's shoulder where he received the flu vaccination. *Id.* When she was asked how long petitioner complained about his shoulder pain and dysfunction, she replied that "it was a good while." Tr 58.

4. Testimony of Ms. Tammy Steele

Ms. Tammy Steele, petitioner's sister, had written a letter stating that petitioner received a flu shot on October 20, 2015 and that "he was complaining about his arm being very sore shortly after he got the shot." Pet. Ex. 16 at 7. In the letter, she also stated, "He called the doctor's office within 48 hours to tell them about the pain. They told him to take Tylenol for pain." *Id.*

Ms. Steele testified that she also attended the family lunch the day the petitioner received the vaccination, on October 20, 2015. Tr. 63. She explained that petitioner was "complaining about [his shoulder] hurting soon after he got there, and it continued to hurt him." Tr. 64. She testified that the family would gather for lunch for years at their mother's house. *Id.* Ms. Steele explained that these lunchtime gatherings would consist of "Shirley, Diana, Jim, Lori, and…our mother." *Id.*

Ms. Steele testified that on October 20, 2015, she was at the family lunch because she had to take care of her mother. *Id.* at 64. She stated, "So when [petitioner] came down from having his flu shot, he was complaining about it not too long afterwards." *Id.* She testified that the petitioner said, "my arm just really hurts from that flu shot." *Id.* at 65. Ms. Steele also testified that at lunch the following day, October 21, 2015, she recalls petitioner complaining about his arm being "sore and achy." *Id.* She stated that between October 20, 2015, and the last day of October, she recalls "multiple times" where petitioner had complained that his shoulder was still hurting him. *Id.*

Ms. Steele also stated that petitioner had shown her on his arm where the pain was coming from. Tr. 65. She stated that "it was….above where…the fatty tissue is. It was above

that area." *Id.* She also testified that there was a mark on his arm." *Id.* at 66. When asked where the mark was on petitioner's arm, she stated that "it was above," the muscle and fatty tissues on the arm. *Id.* During cross-examination, Ms. Steele stated that mark she had seen was a "red spot," that was the size of a pinpoint. *Id.* at 67-68.

5. Testimony of Ms. Diana Mills

Ms. Diana Mills, petitioner's sister, testified that the day petitioner received his flu shot, October 20, 2015 was a Tuesday, and she was at lunch at her mother's house that day. Tr. 71. She stated, "I remember him coming in that day, and he said that he had just gotten his flu shot, and that it was really sore. It hurt really bad." *Id.* She explained that petitioner complained about his arm being sore every day that week during the lunches. *Id.* at 72. Ms. Mills testified that petitioner complained "every day" during lunch that week that his arm was sore. *Id.* She stated, "Like I said, we've been going to lunch at my mother's house for years from 12:00 to 1:00, and the next day, he complained that it hurt just as bad if not more. And then they called the doctor, and they told him to take Tylenol." *Id.* Ms. Mills also stated that between October 20th through the end of October, when asked about his arm, "[petitioner] would tell us every day that it hurt bad." *Id.* When asked if petitioner's pain was getting progressively worse, Ms. Mills stated, "I believe so. Yes. He couldn't move his arm. He couldn't really lift it." *Id.*

She testified that she did not recall if petitioner showed her where the shot was given on his arm, but she remembered him touching his upper arm, "like near his shoulder." *Id.* Ms. Mills was asked if she knew how petitioner's arm pain was affecting his life and she testified that he stopped hunting and fishing. *Id.* at 73. She also explained that petitioner "slept in a recliner because it was more comfortable," and that petitioner stopped working. *Id.* at 74.

During cross-examination, when asked by respondent's counsel if she had an independent recollection of what she wrote in her "To Whom It May Concern" letter about January 20, 2016, Ms. Mills replied, "I had a recollection of it, because lunchtime is when they would call the doctor. So, I knew that he had called, and they said to take Tylenol. I knew about the physical therapy, and I knew that he was getting other shots. So, I didn't really know what they were called, so I asked what [the shots] were called." *Id.* at 76.

Ms. Mills testified that petitioner had full use of his arm prior to receiving the flu vaccine and that after the vaccination he had to limit recreational activities, such as fishing and hunting. Tr. 73.

III. Expert Opinions Regarding Vaccine Causation

a. Petitioner's Experts' Opinions on Causation

1. Dr. Catherine Shaer's opinion

In her first report, Dr. Catherine Shaer explained that she had previously worked at the Division of Injury Compensation Programs ("DICP") and has reviewed "the medical records of

dozens of individuals asserting a Shoulder Injury Related to Vaccine Administration ("SIRVA")." Pet. Ex. 14.

Dr. Shaer explained that the *Atanasoff et al.*[8] paper proposes that "the mechanism for injury is the unintentional injection of antigenic material into synovial tissues resulting in an immune-mediated inflammatory reaction." *Id.* at 1. She stated, "While I fully agree that injection of antigenic material into the synovial tissues can cause an inflammatory response that can lead to SIRVA, I do not believe that this is the only way SIRVA can develop." *Id.* at 2. Dr. Shaer explained that needles from 5/8 inches to 1½ inches are recommended for vaccines intended to be administered intramuscularly, while needles 3/8th inches to 5/8th inches are recommended for vaccines intended to be administered intradermally. *Id.* at 2. She wrote, "Ultrasound measurements have shown that the sub-deltoid bursa is between 0.8 cm (.0315 inches) and 1.6 cm (0.630 inches) below the surface of the skin. I take a very basic view of the issue and see it as one of geometry: a needle 0.375 inches in length can reach a structure 0.315 inches below the skin." *Id.*

Dr. Shaer explained that she did not believe that the only mechanism of injury for a SRIVA is that an improperly administered vaccine enters the sub-deltoid bursa and causes an inflammatory bursitis, but that a vaccine administered abnormally high, near the AC joint, may cause inflammation near the AC joint and the supraspinatus and biceps tendons. *Id.* She concluded her first report by stating, "it is clear that improperly administered intradermal vaccines can be injected into tissues that were not meant to receive the antigen and can cause an inflammatory reaction." *Id.*

Prior to Dr. Shaer filing her supplemental expert report, respondent had filed the Fluzone Intradermal Fact Sheet, which indicated that it was the "first influenza vaccine licensed in the United States that uses a new microinjection system for intradermal delivery of vaccine." Resp. Ex. H at 1.[9] The fact sheet further states, "The microinjection system uses an ultra-thin needle of 0.06 inches (1.5 mm) in length, or less than one-tenth the length of the standard needles used for the traditional intramuscular route of administration." *Id.*

In her supplemental report addressing the length of needle used by the microinjection system for Fluzone, Dr. Shaer reiterated her opinion that "injection into synovial tissue is not the only mechanism of injury [for SIRVA]." Pet. Ex. 17 at 1. She wrote, "Tendinitis (an inflammation of the tendon) is very commonly found in individuals who meet the Table criteria for SIRVA, and it is absolutely seen in individuals with bursitis as well as those with no evidence of bursal involvement. The question then becomes not only how long a needle has to be to reach the bursa, but also how long it has to be to reach the tendons that lie much closer to the surface." *Id.* at 1-2. Dr. Shaer noted that some studies have measured skin thickness, such as the *Laurent et al.* article which examined skin thickness of adults to assess the appropriate microneedle

[8] Atanasoff, S. et al., *Shoulder injury related to vaccine administration (SIRVA)*, 28 Vaccine 8049-52 (2010). [Pet. Ex. 21].

[9] Fluzone Intradermal (Influenza Virus Vaccine), Facts at a Glance. [Resp. Ex. H].

length for intradermal delivery of vaccines. Pet. Ex. 22.[10] The authors explained that intradermal vaccine delivery for the flu vaccine was being investigated and wrote, "Dermal tissue is considered to be an appropriate site for antigen presentation as it contains dendritic cells, macrophages, lymphocytes and a dense network of blood capillaries and lymphatic vessels that play a key role in the circulation of immune-competent cells." *Id.* at 1. The authors further noted that, "numerous studies have reported an improved immune response resulting in decreased antigen dose requirements relative to standard immunization." *Id.* The article stated that the 1.5 mm microneedle was developed for intradermal flu vaccine administration and various body sites were being explored for intradermal vaccine administration, including the upper arm, suprascapular region, the lower quadrant of the abdomen, and the anterior lateral area of the thigh. *Id.* The article stated, "These sites were selected because of the dense lymphatic draining nodes in axillary and neck areas, and ease of access for vaccination." *Id.*

The authors of *Laurent* examined the skin thickness in 137 men and broke their results down by age, finding that participants between the ages of 51-70 years old have a skin thickness mean of 2.13 mm. *Id.* at 4. The authors also found that the skin thickness at these sits can vary by a person's weight. *Id.* at 4. An individual who was considered "underweight" in the study was found to have a skin thickness of approximately 1.75 mm to 2.11 mm. *Id.* The authors concluded that the appropriate location for an intradermal vaccination into the dermis would be in the deltoid, suprascapular and waist locations. *Id.* at 6. Dr. Shaer observed that petitioner was 58 at the time of vaccination, which would put his skin thickness between 1.98 mm thick and 2.28 thick. Pet. Ex. 17 at 2.

Dr. Shaer concluded that "it is reasonable to conclude that it is possible for a misplaced injection, even when administered with a microneedle, to reach structures that can respond with severe inflammation resulting in SRIVA." *Id.* at 3.

2. Dr. Uma Srikumaran's opinion

Dr. Srikumaran stated that, "the medical records, as well as statements from [petitioner], his friends and his family, strongly suggest his right shoulder dysfunction was caused by the October 20, 2015 vaccination." Pet. Ex. 25 at 5. During the hearing, Dr. Srikumaran explained that a SIRVA refers to "the shoulder condition that can result after a vaccination, so the theory being an antigenic material is injected into or near the subacromial bursa, causing a significant inflammatory response, thereby leading to pain and shoulder dysfunction, such as limited range of motion or weakness, and pain with various activities." Tr. 89. He stated that common characteristics of a SIRVA are "consistent with the presentation with a bursitis or tendonitis of the shoulder…pain in the lateral aspect of the shoulder, with immediate or tight time correlation to the time of their vaccination, a consistent recalling of the events and reporting to various providers." *Id.* at 90. He also stated that typical findings or signs of SIRVA include pain, pain at night in the shoulder, difficulty using the shoulder away from the body, and limited range of motion over time. *Id.*

[10] Laurent A., et al., *Echographic measurement of skin thickness in adults by high frequency ultrasound to assess the appropriate microneedle length for intradermal delivery of vaccines*, 25 Vaccine 6423-39 (2007). [Pet. Ex. 22].

Dr. Srikumaran acknowledged that petitioner received an intradermal flu vaccine and he agreed with Dr. Shraer, that the receipt of the intradermal vaccine does not automatically invalidate a SIRVA injury claim. Pet. Ex. 25 at 7; Tr. 95. He explained that an intradermal vaccine is intended to be deposited into the dermal layer of the skin, differing from the intramuscular vaccination, "which is intended for injection directly into the muscle." Tr. 90. He stated, "While the intradermal vaccination is *designed* to enter the dermal layer, *technique* can lead to a deeper injection location such as the muscle." Pet. Ex. 25 at 7. While Dr. Srikumaran agreed with respondent's expert, Dr. Schroeder, that the 1.5 mm intradermal needle is unlikely to reach the rotator cuff, he also agreed with Dr. Bodor's opinion that a needle can reach a further depth by pressing firmly into the tissue. Pet. Ex. 25 at 8. Dr. Srikumaran testified that "any type of needle can be used with variable force as its injected into the skin and into the body….The body's quite compressible at various layers, so you can advance the needle further through the body with increased force." Tr. 97.

Additionally, Dr. Srikumaran argued that "the length of the needle may not be as important as the antigen, or the material being injected." Tr. 102. He asserted that the intradermal needle could cause inflammation the same way that an intramuscular needle can cause inflammation. *Id.* He explained that if an intradermal vaccine administrator were to inadvertently push harder on the intradermal injector than recommended, it would "….allow for and account for an intramuscular injection and because inflammation often does not simply localize to a small defined area, rather it often occurs in a generalized area, a focus of inflammation in the muscle can affect the surrounding structures, including the bursa and rotator cuff tendon, leading to bursitis and tendonitis." Pet. Ex. 25 at 8.

During the hearing, he reiterated this theory and stated:

> ….there's also a possibility that [the intradermal injection] can be injected deeper into the muscular layer, and once injected there, the antigen or infiltrate that's injected can go to the depth of the muscle. Any types of defects or inflammatory reaction in that area of the muscle can spread to adjacent structures. The subacromial bursa is immediately adjacent and touching the undersurface of the deltoid muscle. So, the mechanism that's theorized to cause SIRVA is potentially feasible in an intradermal case as well.

Tr. 96.

He explained that "the inflammatory response typically does not restrict itself to areas as small as millimeters or centimeters." Pet. Ex. 25 at 8; Tr. 100. Dr. Srikumaran testified that an infiltrator can drift into other areas and that the infiltrator spreads along "tissue planes or paths of least resistance, so if there are even the slightest defects in the muscle, you can go into deeper planes." *Id.* He also explained that the body's response to the infiltrate, the antigen in the vaccine, is inflammation and that the inflammation is "not limited to one level or one structure." *Id.*

Dr. Srikumaran used the example of a bee sting to demonstrate how inflammation can spread. Tr. 100; Pet. Ex. 25 at 8. He stated, "Interestingly, bee and wasp stingers have been studied for the purpose of designing microneedle injecting devices. Inflammation is well known

to be capable of growing and spreading to adjacent structures as commonly occurs after bee or wasp stings." Pet. Ex. 25 at 8. Dr. Srikumaran testified that, "At times, [the bee sting] can cause a small amount of inflammation, but depending on the host, it can also cause a significant amount of inflammation involving an entire extremity, and that inflammation can start at a local site and spread to adjacent structures." Tr. 100.

In response to a question from the Court about whether an inflammatory response can spread without having direct contact with a foreign antigen, Dr. Srikumaran responded, "I do think the inflammation can spread without the antigen necessarily directly spreading to adjacent structures….we see that frequently in the shoulder, again because…these structures are quite contiguous and kind of flow from one another, so the subacromial bursa connects to the subdeltoid [bursa], all the way into the joint, particularly in the situation where you have a rotator cuff tear." Tr. 112. He also stated that when there is wear and tear, there are pathways that inflammation, which was initially a response to the antigen, can spread through the worn structures and cause downstream structures to become inflamed and painful. *Id.* Dr. Srikumaran also explained that the location in which the petitioner stated he received the vaccine was the area where the deltoid muscle is the thinnest and the bursa is closer to the surface of the skin. Tr. 112-14. Dr. Srikumaran testified that, "The area closest to the acromial bone appears to have the highest risk of developing SIRVA." Tr. 114. He noted that the deltoid muscle is thicker as it gets further down the arm, but the bursa is closest to the subacromial area just under the acromial bone, making it more susceptible to inadvertent injection or inflammation. *Id.*

Dr. Srikumaran opined that the cause of shoulder dysfunction related to vaccination is the *initiation of inflammation* directly related to vaccine antigen being delivered to or near the bursa or synovium of the joint. It is *this inflammation which initiates pain* in previously long standing, silent chronic degenerative conditions." Pet. Ex. 25 at 8 (original emphasis). He testified that the vaccination did not directly cause the rotator cuff tear, but "the mechanism of action for this condition is the triggering or initiation of inflammation of structures that are immediately adjacent to the rotator cuff." Tr. 98.

Dr. Srikumaran observed that the authors of the *Atanasoff* article proposed that the mechanism of injury for post-vaccination shoulder pain and dysfunction was an immune-mediated inflammatory response if the vaccine was inadvertently injected into the bursa or joint of the shoulder. Pet. Ex. 21 at 3. In the *Atanasoff* article, the authors examined thirteen cases of shoulder pain and dysfunction following vaccination. *Id.* at 1. They found that nearly half of the patients voiced concerns that the vaccine was administered "too high" in the deltoid and onset of pain occurred within 24 hours of vaccination in 93 percent of the cases. *Id.* The authors theorized, "Although shoulder dysfunction due to mechanical or overuse injury is always a diagnostic consideration, the rapid onset of pain with limited range of motion following vaccination in our series of patients is consistent with a robust and prolonged immune response within already-sensitized shoulder structures following injection of antigenic substance into the subacromial bursa or the area around the rotator cuff tendon." *Id.* at 3. Additionally, the authors noted that MRI findings included bursitis, tendonitis, rotator cuff tears, and fluid collections in the deep deltoid or overlying the rotator cuff tendons. *Id.* at 2. They opined that some of the MRI findings, such as rotator cuff tears, may have been present prior to vaccination and became symptomatic as a result of vaccination associated synovial inflammation. *Id.* at 3.

During the hearing, Dr. Srikumaran explained that the "bursa is closest to the subacromial area just under the bone and up higher," where the deltoid muscle is not as thick, which is why "the area closest to the acromial bone appears to have the highest risk of developing SIRVA." Tr. 114. The article by *Hesse et al.,* examined 476 petitioner claims in the VICP where the government conceded cases to find common characteristics. Pet. Ex. 31 at 1.[11] The article was consistent with the *Atanasoff* article, finding that the common MRI characteristics were tendonitis, tendinopathy, complete or partial rotator cuff tears and bursitis. *Id.* at 4. Additionally, the authors found that 75.8% of petitioners reported that the vaccine was given "too high," again consistent with the *Atanasoff* article. *Id.* at 5. The authors provided a broad definition of "SIRVA," stating, "SIRVA can be broadly defined as pain that begins within 48 hours of vaccination and reduced range of motion." *Id.* at 6. They stated that "such a broad definition makes it difficult to describe SIRVA as a discrete clinical entity," but that common initial diagnoses were rotator cuff problems and bursitis. *Id.*

Dr. Srikumaran cited the article by Drs. Bodor and Montalvo, where they hypothesized that the vaccine was injected into the subdeltoid bursa of two patients, causing a robust local immune and inflammatory response. Pet. Ex. 20 at 2.[12] The authors explained, "Given that the subdeltoid bursa is contiguous with the subacromial bursa, this led to subacromial bursitis, bicipital tendonitis, and inflammation of the shoulder capsule." *Id.* The authors also noted that both patients' problem involved multiple shoulder structures-the subacromial space, the bicipital tendon and the glenohumeral joint. *Id.* at 2. The *Bodor* article explained that both patients required multiple steroid injections for the pain to resolve, which they found to be "consistent with a primary inflammatory etiology rather than a mechanical overuse problem." *Id.*

Dr. Srikumaran cited another article by *Hesse et al*., which found an additional 7.78 cases of bursitis occurred within the three days after vaccination for every 1 million persons vaccinated with the flu vaccine. Pet. Ex. 32.[13] The researchers looked at nearly 3 million people who received the flu vaccine in 2016-2017 flu season and identified 1098 presumptive cases of bursitis. *Id.* at 4. They randomly selected 526 presumptive cases for medical record abstraction and found that 421 had definite diagnosis of subdeltoid bursitis with 16 cases having symptom onset from 0-2 days after vaccination. *Id.* The authors concluded, "We identified a small risk for subdeltoid bursitis with new symptom onset after injection of an influenza vaccine. This study provides epidemiologic evidence of an association that was previously supported by clinical evidence from case reports." *Id.* at 7.

Dr. Srikumaran stated that the flu vaccine triggered an immune-mediated inflammatory response in and around the area of injection that spread into petitioner's subacromial bursa and around the rotator cuff tendons, presenting as bursitis and tendonitis. Pet. Ex. 25 at 9; Tr. 115.

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[11] Hesse, E. et al., *Shoulder Injury Related to Vaccine Administration (SIRVA): Petitioner claims to the National Vaccine Injury Compensation Program,* 38 Vaccine 1076-1083 (2020). [Pet. Ex. 31].

[12] M. Bodor, *Vaccination-related shoulder dysfunction,* 25 Vaccine 585-87 (2007). [Pet. Ex. 20].

[13] Hesse, E., et al., *Risk for Subdeltoid Bursitis After Influenza Vaccination,* 173 Ann. Intern. Med. 253-61 (2020). [Pet. Ex. 32].

Dr. Srikumaran stated that it was likely petitioner had pre-existing rotator cuff disease which was asymptomatic. Tr. 99. He noted that "most people his age, will have findings of chronic degenerative conditions such as frayed or partially torn ligaments and tendons…However, the majority of these chronic conditions are asymptomatic." Pet. Ex. 25 at 8. He stated that, "The salient point in these cases is not whether there are chronic conditions present, but rather, what caused or 'triggered' a previously asymptomatic chronic condition to become painful." *Id.* Dr. Srikumaran observed that the medical records in this case support a consistent onset of pain, without any other intervening injury or triggering event. Pet. Ex. 25 at 10.

Additionally, Dr. Srikumaran opined that an appropriate timeframe for the onset of symptoms post-vaccination is from two days to two months. Tr. 95. He cited to the *Arias et al*. article which reviewed the current medical literature of post-vaccination related bursitis and other shoulder injuries and the Spanish version of VAERS ("FEDRA") to identify characteristics and potential causes of post-vaccination shoulder injuries. Pet. Ex. 27.[14] The authors found that much of the existing literature described that the "vaccine had been administered into a 'very high site' in the arm, at a distance between 1 and 3 cm of the acromion." *Id.* at 5. Further, the authors found that the "systemic review showed that the patients had immediate pain or pain arising within the first 24 hours post-vaccination in 81.1% of cases, while the remaining 18.9%, had pain within the first four days. The pain was of increasing severity and caused shoulder mobility restriction." *Id.* at 3. In the authors review of the FEDRA cases, "6 out of 8 patients complained of increasing severity of pain starting within the first 24 hours or few days (4-7 days) post-vaccination, and 2 cases reported pain within 2 months." *Id.*

Dr. Srikumaran concluded that he did not believe that the intradermal flu vaccine caused petitioner's rotator cuff tear, but that the vaccine triggered an inflammatory response in and around the muscle that caused inflammation of the tendons and the bursa, causing pain and dysfunction, which appeared as bursitis and a symptomatic rotator cuff tear. Pet. Ex. 25 at 10; Tr. 117.

3. Dr. Marko Bodor's opinion

Petitioner also sought the opinion of Dr. Marko Bodor to support his claim. Dr. Bodor explained that his article first described the original mechanism for SIRVA. Pet. Ex. 18.

Dr. Bodor stated that, "When antigenic material is injection into the deltoid muscle, it causes an immune response and inflammation. Inflammation causes pain….The degree of pain varies between individuals and the degree of inflammation varies from mild to severe depending on an individual's previous immune exposures and other factors." *Id.* at 2. He wrote that the deltoid and rotator cuff muscles each provide approximately 50% of shoulder abduction power, and if there is pain in the deltoid muscle, there will likely be a greater load on the rotator cuff muscles. *Id.* The greater load on the rotator cuff muscles could initiate a new or extend a pre-existing rotator cuff tendon tear. *Id.* Dr. Bodor also noted that an injection high into the shoulder is part of the mechanism he described in his article. Pet. Ex. 18 at 1.

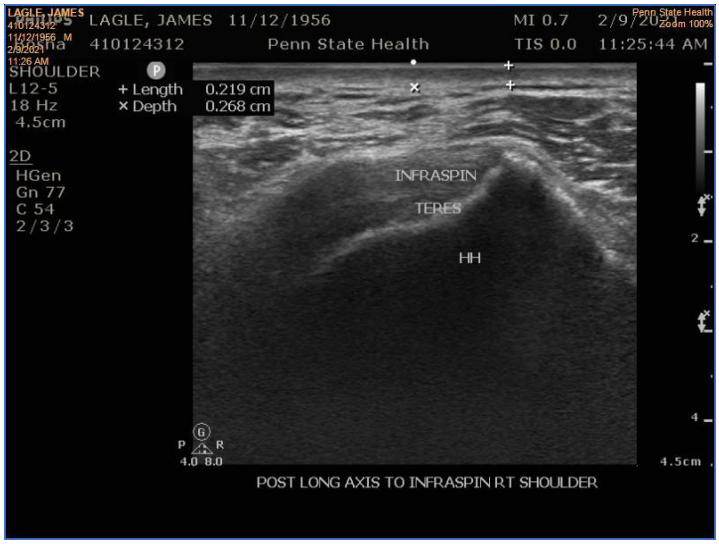
[14] Arias, L.H. et al., *Risk of bursitis and other injuries and dysfunctions of the shoulder following vaccinations*, 35 Vaccine 4870-76 (2017). [Pet. Ex. 27].

During the hearing, Dr. Bodor testified that he agreed with Dr. Srikumaran's opinion as to how the intradermal flu vaccine caused petitioner's shoulder injury and added that it was his opinion that petitioner "had an inflammatory reaction that extended into his deltoid muscle and potentially into the adjacent bursa. That predisposed to possibly frozen shoulder that started around two or three weeks later or potentially exacerbated a preexisting rotator cuff condition." Tr. 134.

When asked by counsel how could an intradermal needle cause a person to suffer shoulder injury due to vaccine administration, he stated that, "It depends on how hard you press and how you depress this plunger." Tr. 135. Dr. Bodor performed a demonstration using a 12.5 mm length needle with 0.1 mls of water and stated, "…if I press this [plunger] with reasonable force, I can make the volume squirt three feet. If I can get three feet through the air, how much can I get to go through muscle tissue that's maybe three or four millimeters away from the bursa?" After Dr. Bodor's demonstration, he stated, "I believe that a 1.5 mm needle could definitely go through the skin and reach the deltoid muscle." He testified that how far one of these microneedles can go into the arm depends on how much force is exerted on the plunger. Tr. 154.

During cross-examination, Dr. Bodor conceded that he used a syringe during his demonstration and not the "microinjection system" used to deliver the intradermal Fluzone. Tr. 153. However, he also stated that the microinjection systems are not available anymore, and therefore he could not perform a demonstration with the exact microinjection system. *Id.* at 154. Further, Dr. Bodor acknowledged that during his demonstration, air resistance is different than "standard body tissue." He also conceded that he did not know if the antigen from the intradermal vaccination could actually reach the bursa. Tr. 153. He noted that the bursa was approximately 8 mm below the skin's surface. Tr. 154.

Dr. Bodor also reviewed petitioner's shoulder ultrasounds during his testimony. Tr. 138. Looking at petitioner's exhibit 37, reproduced below, Dr. Bodor noted that the petitioner's skin, which was measured just below the acromion bone was measured at 0.219 cm or 2.1 mm thick. Tr. 139. He also explained that below the two plus signs on the image, lays the deltoid muscle and the infraspinatus tendon sits below the deltoid muscle. *Id.* The "HH" marked on the image is the greater tuberosity of the humerus which appears as the dark peak on the ultrasound. Tr. 142.



Pet. Ex. 37 at 1. Dr. Bodor testified that "the distance to the deltoid muscle (from the skin) is 2.1 mm at the high point in the shoulder where the injection was given and if the needle is compressed, the skin will compress by 50 percent or so. So, we can expect that the skin thickness can be reduced to 1 mm, and you can definitely penetrate that deltoid muscle." Tr. 139. He opined that if "somebody goes ahead and just pushes it in quickly….it may go down to the bursa, which is actually about three times the distance….another 6 mm." Tr. 140. Dr. Bodor explained that the bursa is a layer between the tendon and the muscle on the image above, and he estimated there was approximately 8 mm between the skin and petitioner's bursa. *Id.*

Dr. Bodor testified that based on the petitioner's skin thickness "the injection could have definitely gone into the deltoid muscle…and so we could have deltoid muscle inflammation, and just by virtue of a vaccine causing a normal immune response, and a sore shoulder, which any vaccine can do." Tr. 144. He stated that he agreed with Dr. Srikumaran's opinion that "if the deltoid muscle is full of pain and inflammation, it can change the recruitment of the…muscles in the shoulder." *Id.* He testified that it was a "known phenomenon" that if one body part hurts, then a person is not going to move it and "then you're going to activate other muscles as compensation." *Id.* at 145. Dr. Bodor stated that "if the deltoid is not activating because it's in pain, you may over activate the rotator cuff, and if you now have some pre-existing tear, you might be increasing that tear or you might cause more strain on that rotator cuff." *Id.* Dr. Bodor also stated that there was "no objective evidence" that petitioner had rotator cuff problems prior to his vaccination. *Id.* at 146.

He also opined that a second mechanism to cause a shoulder injury after an intradermal vaccination is "generalized inflammation in that area that can persist and just cause pain and eventually cause a frozen shoulder." Tr. 145. Dr. Bodor stated that this "potentially could have happened in this case, that [petitioner] started to get a little frozen shoulder around two weeks [after vaccination] or so." *Id.*

Dr. Bodor explained that petitioner's characterization "from soreness to pain" after a couple days post-vaccination is consistent with vaccinations in general. Tr. 147. He used the example of the COVID-19 vaccines, stating that "at the beginning [one] may have some soreness

just from the needle having gone in, but the real pain starts about six to ten hours later when your body reacts to the antigens….creating an immune response against these antigens." *Id.* He continued, "So in the beginning, you may just feel the shot itself, just the needle, but then you may get more pain as the immune system starts to kick in and create an inflammatory reaction against the antigens." *Id.*

Dr. Bodor concluded that the intradermal flu vaccine that the petitioner received caused an inflammatory response, which led petitioner to have shoulder pain and dysfunction. Pet. Ex. 17 at 2; Tr. 150.

b. Respondent's Experts' Opinions Regarding Intradermal Vaccine Causation

1. Dr. Harry Schroeder's opinion

Dr. Schroder opined that petitioner developed right shoulder pain from rotator cuff tears in November 2015, but that this pain was not attributable to the Fluzone vaccine he received on October 20, 2015. Resp. Ex. A at 9. He stated that, "the only association between [petitioner's shoulder injury and flu vaccine] is temporal." Tr. 171. He stated that petitioner's theory was "implausible, and…most likely is totally unlikely." Tr. 174.

Dr. Schroder explained that rotator cuff tears are common and degenerative rotator cuff tears are commonly seen in the aging population. Resp. Ex. A at 7. He also noted that it was difficult to establish the precise date of a tear because "most are asymptomatic," and progress in size which is when they become painful. *Id.* Dr. Schroder observed that petitioner's MRI showed moderate acromioclavicular joint degenerative change, which Dr. Schroeder attributed to petitioner's occupation and other health issues.

Dr. Schroeder described the mechanism for an intramuscular SIRVA injury utilizing a one-inch needle, stating that if the vaccine is administered "a little higher" on the shoulder, "then the one inch is long enough to penetrate through the muscle and into the synovial space." Tr. 172. He explained that this introduces an "antigen in an area that's normally devoid of antigen, so you're going to start a local inflammatory reaction which will occur within 48 hours of the activation of the innate immune system. That inflammation will lead to pain, and it can ultimately lead to scarring, loss of tissue, and joint destruction if it's severe enough." *Id.* Then he stated that in this case, it is implausible and "most likely totally unlikely," that it could occur with an intradermal vaccination. *Id.* Later in the hearing, he clarified that it is not "just the needle going in," that causes a SIRVA, but that, "It's the antigen that is initiating the immune response….It's the wrong compound in the wrong place." Tr. 207.

In his expert report, Dr. Schroeder explained that the Fluzone vaccine utilized a "microinjector system specifically designed to deliver the vaccine…only into the dermis." Resp. Ex. A at 8. He stated that the microinjection system, "employs a tiny hollow microneedle that penetrates 1.5 mm into skin from the outer skin surface to deliver a volume in the range of 100-200µl. *Id.* During the hearing, Dr. Schroeder testified that the applicator for the intradermal flu vaccine that was administered to petitioner was "specifically designed to prevent…going beyond the skin." Tr. 204. Dr. Schroeder stated that the "skin has been recognized as a potentially

excellent site for vaccination." *Id.* at 7. Dr Schroeder referenced the *Lambert et al.* article, which explored why and how intradermal vaccines can be used as an option to increase immune response utilizing a decreased dose of antigen and to increase vaccination safety. Resp. Ex. E.[15]

Lambert explained that the skin is composed of three main layers, the epidermis, the dermis and the hypodermis. *Id.* at 4. The skin generates both innate and adaptive immune responses. *Id.* The authors stated, "The key group of immune cells involved in the skin's innate immune response is dendritic leukocytes: Langerhans cells in the epidermis and dermal dendritic cells in the dermis," and both of these cells are "bone marrow-derived leukocytes highly specialized in antigen presenting properties," which "play a pivotal role in the induction of adaptive immune response against pathogens and any other antigens…which compromise the host homeostasis." *Id.* at 5. Further, the authors explained that the microinjection system utilizes a "microneedle" that is supposed to penetrate 1.5 mm into dermis layer. *Id.* at 8. They noted that while the microinjection system was in phase 2 studies in adult volunteers, "the humoral immune responses was comparable to those obtained by the standard intramuscular route, but with a lower antigen dose." *Id.* The authors stated that the "local adverse events were equivalent to the IM route except for more frequent edema and redness at the site of injection, but with the absence of post immunization muscle pain." *Id.*

Dr. Schroeder testified that one may see an inflammatory response to the intradermal vaccine at the site of injection. Tr. 178. He explained that "the skin is full of antigen presenting cells and T-cells…so the antigen presenting cells will grab the antigen, and they will take it into the lymph nodes that are draining that portion of the skin, and there within the lymph node, you'll elicit a T and B cell reaction." *Id.* He stated that he would not expect that the inflammatory response, however, to extend into the subacromial bursa. Tr. 179. He testified that "this reaction is mostly confined to the skin and perhaps a little bit underneath." *Id.* Dr. Schroeder stated that the distance involved between the skin and subacromial bursa is separated by the three layers of skin (epidermis, dermis, and hypodermis), then adnexal tissue where the fat is located and if over a muscle, there is fat fascia over the muscle, then the muscle itself. *Id.* He also stated that there is a glue-like substance called hyaluronic acid that is holding the muscle to the skin. *Id.* He explained hyaluronidase is used to dissolve the hyaluronic acid to improve the absorption of medicines that are injected subcutaneously. *Id.* In response to Dr. Srikumaran's testimony regarding inflammation spreading after a bee or wasp sting, he testified that "one of the parts of the venom of the bee sting is hyaluronidase, so that there is more of a flow of the venom into the surrounding area and increase the pain and discomfort." *Id.* He stated that even if the intradermal vaccine punctured the skin the antigen would "be primarily confined in the space between the muscle and the skin. It's highly unlikely that it'll go into the muscle." *Id.*

Dr. Schroeder stated that local inflammation is the first thing one might expect after an intradermal vaccination. Tr. 184. The signs of local inflammation include pain, redness, swelling, and loss of function. *Id.* However, he asserted, "when you're dealing just with the skin, there is no loss of function, but you do see the pain and swelling and redness." *Id.* Dr. Schroeder opined that petitioner's reporting of local pain, local redness, and a mark where the vaccine was administered was "exactly what you'd expect to see if you had a reaction to the

[15] Lambert, P. and Laurent, P., *Intradermal vaccine delivery: Will new delivery systems transform vaccine administration?* 26 Vaccine 3197-3208 (2008). [Resp. Ex. E].

intradermal vaccine." Tr. 185. The reason the area gets red, according to Dr. Schroeder, is because more blood and fluids "flood the area," which also explains why the area of injection gets swollen within 48 hours. *Id.* He stated that the area is not only going to have increased fluid, "but it's going to have a lot of T cells that rushed in there to fight off what they thought was an infection, so the area will also be hard." *Id.* Dr. Schroeder asserted that what petitioner had described was "just a strong response to the vaccine, local response to the vaccine, which is typical of such a vaccine." *Id.*

Dr. Schroeder was asked if petitioner's medical records indicated if inflammation had extended beyond the site of the vaccination, Dr. Schroeder responded, "…there's nothing in the record that I saw, other than the fact that there was a mark at the site of the injection, that indicates that there was continuing inflammation, especially there's nothing here that says that there was inflammation of the muscle." Tr. 187. Dr. Schroeder stated that he would expect that pain associated with inflammation to begin within 48 hours of vaccination, because "the SIRVA injury is due to the initiation of an innate response." Tr. 189-90. It was also his opinion that pain would not appear "two to three weeks later." Tr. 190.

During cross-examination, when Dr. Schroeder was asked if he had an opinion about when the onset of petitioner's pain was after he had heard the testimony of petitioner and the fact witnesses, he stated, "I think that he had a local reaction to the vaccination, which is well within the bounds of what I expect in that type of vaccination and that two weeks later, and totally unrelated, he suffered symptoms from a tear in the rotator cuff that he may or may not….have had before." Tr. 195. Dr. Schroeder clarified that he believed that petitioner had a pre-existing rotator cuff tear, which was consistent with what he wrote in his second report. He stated that it was his opinion that "neither the pain that appeared in November 2015, nor the tears that were first documented in March of 2016 were caused by the Fluzone vaccine [petitioner] received on October 20, 2015. Resp. Ex. I at 4. Dr. Schroeder stated that "there's a number of people walking around with asymptomatic rotator cuff injuries." Tr. 200.

When petitioner's counsel questioned if Dr. Schroeder could identify any other event in the medical records that would have caused petitioner's acute onset of pain, Dr. Schroeder conceded that, "There was no other description of an inciting event." Tr. 202. Later, Dr. Schroeder was asked how he would explain the onset of petitioner's shoulder soreness and pain after the vaccination and he responded, "I can attribute what happened within the first 48 hours to the vaccination quite easily…..I don't see how the local inflammation, which would have resulted from the vaccination, would have extended to the deltoid muscle." Tr. 220. Dr. Schroeder stated, "The soreness and pain within 48 hours is certainly plausible, even likely, that it occurred as a result of the vaccination." Tr. 221.

2. Dr. Paul J. Cagle, Jr.'s opinion

Dr. Cagle stated that he does not believe that the vaccine caused petitioner's right shoulder injury. Tr. 226; Resp. Ex. J at 6. In his report, Dr. Cagle stated that, "The proposed mechanism of a 1.5 mm needle penetrating all the way into the deltoid muscle is not supported by any reliable evidence. Therefore, I cannot find a medical causal link between the vaccination injection and subsequent shoulder pain and surgery required in this case." Resp. Ex. J at 6.

Dr. Cagle testified that it was incredibly implausible that the vaccine was injected into petitioner's arm and the material went through the deltoid and into the bursa. Tr. 226. However, he also testified that it was "theoretically possible" that a 1.5 mm needle could penetrate to "at least the tip" of the deltoid muscle under the skin at the location identified on petitioner's exhibit 37. Tr. 240. But he questioned how much further the needle could penetrate because there is a plastic hub. *Id.* He testified that if the needle could go down "two to three times its length, to some degree just to get through a little bit of fatty tissue…that would have obviously needed to be pressed incredibly hard, which would theoretically and likely have caused some degree of tissue trauma due to the plastic edge" around the needle. Tr. 242. He observed that there was not any testimony consistent about breaks in the skin, cuts or bleeding that would be consistent with a "penetrating type trauma," from the plastic hub. Tr. 241-42. Dr. Cagle also wrote in his report, "Although I cannot rule out the possibility that a very firmly pressed 1.5 mm needle can penetrate an additional 0.6 mm…there would be a layer of adispose tissue (fatty tissue) between the deltoid and the skin." Resp. Ex. J at 4. He concluded that he had "no evidence to support [petitioner's] theory" that the 1.5 mm needle could push through both the skin and the fatty tissue to deposit the antigen into the deltoid muscle causing an inflammatory response. Resp. Ex. J at 4-5.

Later, he testified that he did not believe it would be possible for the vaccine contents to spread into and through the deltoid muscle. Tr. 246. It was his opinion that it was not likely that the "contents of something being shot into the skin would then spread through the deltoid and into the bursa." Tr. 248. He testified, "….if we look at how our deltoid is physiologically built, there is a covering of fascia over it, and that's a protective covering that is actually relatively hard and usually requires a scalpel to get through." *Id.* Dr. Cagle stated that fascia is the covering of the muscle that lays between the adipose tissue and the muscle. *Id.* He explained that the fascia gives the muscle structural strength. Tr. 249. When asked whether the fascia or muscle has some degree of mechanical permeability to fluid, Dr. Cagle explained that defects in the fascia are typically the result of a penetrating trauma or surgery, which would create "fascial rents." *Id.* However, he opined, "my understanding of this shoulder here is it was asymptomatic and [petitioner] had no prior significant events to it, so there's no reason to anticipate that fascia was violated." Tr. 250.

Dr. Cagle agreed with Drs. Bodor and Dr. Schroeder that petitioner's rotator cuff tear was pre-existing. Resp. Ex. J at 3; Tr. 230. He stated that petitioner had presented with a partial thickness rotator cuff tear that was previously asymptomatic, which is "one of the most common presentations," he sees in his medical practice. Tr. 230. He also testified that the other reason that he believed petitioner's rotator cuff tear was pre-existing was because the tear "was on the underside of a joint side, a partial thickness tear, the opposite of the side the needle would have come in on." Tr. 231. Dr. Cagle explained that rotator cuff tears occur in the shoulder tendons because of the continuous use of a tendon, developing wear and tear. Tr. 237. He stated that, "The rotator cuff is an area where they have traction or pulling, and the thought is that chronically over time, either via internal mechanical or just structural reasons [it] begins to tear or wear out." Tr. 38. In his report, Dr. Cagle noted that "asymptomatic rotator cuff tears will become symptomatic in on average 2.8 years." Resp. Ex. J at 4. He stated that "the natural history of an asymptomatic rotator cuff tear can be progression to a painful symptomatic

tear/shoulder." *Id.* During the hearing, he explained that there is no identifiable reason that a previously asymptomatic rotator cuff tear becomes symptomatic. Tr. 239.

Dr. Cagle called Dr. Srikumaran's theory that a shoulder injury can occur if the injection is near the bursa, "speculation." Tr. 246. He stated that it's also speculative that "inflammation…presumably near the deltoid….is going to cause an underlying bursal inflammation." *Id.* Dr. Cagle stated that petitioner's MRI did not demonstrate inflammation in the shoulder and petitioner did not demonstrate inflammation when his right arm was moved around for a blood pressure evaluation. *Id.* He explained that if there is inflammation in the deltoid, it will appear as a "signal change" on an MRI. Tr. 243. Dr. Cagle testified that he had reviewed petitioner's MRI and stated that, "It did not mention any acute inflammation in the belly of the deltoid muscle." Tr. 244. He also stated that even if the MRI was taken two to three months later, there would likely be inflammation in the bursal space still evident, but could not answer definitively if inflammation would still be seen in the deltoid on an MRI. *Id.*

In his report, Dr. Cagle observed that petitioner had an appointment on November 10, 2015, three weeks after vaccination, where petitioner had his blood pressure measured on his right arm. Resp. Ex. J at 5; Pet. Ex. 2 at 136. Dr. Cagle wrote that, "The application of the cuff would have required shoulder motion. This was not documented to have caused reported or observed pain at the visit at any time." Resp. Ex. J at 5. Dr. Cagle testified that petitioner's shoulder "certainly did not seem to demonstrate inflammation when [he] moved it around for a blood pressure evaluation." Tr. 246. In Dr. Cagle's opinion, the fact that petitioner had his blood pressure reading taken from his right arm on November 10, 2015, indicated that petitioner was not experiencing any pain in his right shoulder, which did not coincide with his understanding of when onset of pain would begin if someone had a SIRVA. Tr. 245. Dr. Cagle stated that, "In review of the medical literature, multiple case reports have been presented correlating shoulder injuries and vaccinations, but in 16 studies encompassing 36 total patients, all reported patient cases had an onset of symptoms in the first three days." Resp. Ex. J at 5. He testified that, "The vast majority of studies in the literature, actually most people stated [the pain] started within one day, typically less than 24 hours. A large number typically within 48 hours, which seems consistent with what the definition of SIRVA is now." Tr. 245.

One of the articles Dr. Cagle cited was the *Atanasoff* article, which looked at 13 cases of shoulder injury post-vaccination and found that 7 patients had immediate pain, 5 patients reported onset of pain within 24 hours, and one patient reported pain within 4 days of the vaccination. Pet. Ex. 21 at 2. He also cited to the article by *Cross et al.*, which summarized 17 cases of shoulder injuries post-vaccination from other medical articles and found, "Most patients developed pain and reduced range of motion within a few hours of vaccination, although it can be delayed by up to four days." Resp. Ex. EE.[16] The authors of the article also noted that, "Shoulder injury from vaccination is greater than would be expected from a simple needle trauma. An immune-mediated reaction to the adjuvant, antigenic or non-antigenic components of the vaccine have been implicated. A robust and prolonged reaction may be the response of a sensitized population who have antigenic exposure from previous vaccination or previous infection." *Id.* at 4.

[16] Cross, G., et al., *Don't aim too high: Avoiding shoulder injury related to vaccine administration,* 45 AFP 303-306 (2016). [Resp. Ex. EE].

During cross-examination, Dr. Cagle stated that the November 10, 2015 appointment was an opportunity for petitioner to report pain in his shoulder and "provoke the pain," but there was no reporting of pain. Tr. 280. Therefore, in his opinion, the acute onset of pain from petitioner's previously asymptomatic rotator cuff tear did not have a causal link to the vaccination. Tr. 281. Dr. Cagle's opinion was that petitioner's medical records "reflects a timeline from the injection to symptom onset that is not consistent with the medical literature regarding SIRVA." Resp. Ex. J at 6.

Dr. Cagle concluded that petitioner's "proposed mechanism of a 1.5 mm needle penetrating all the way into the deltoid muscle is not supported by any reliable evidence. Therefore, I cannot find a medical causal link between the vaccination injection and subsequent shoulder pain and surgery required in this case." Resp. Ex. J at 6.

IV. Legal Standard for Adjudication

a. Finding of Fact

A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Curcuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19.

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs*., 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391

(citing *Blutstein v. Sec'y of Health & Human Servs*., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

b. Causation

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" *Rooks v. Sec'y of Health & Hum. Servs.*, 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner's burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. *Moberly v. Sec'y of Health & Hum. Servs.,* 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, petitioner must prove that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs*., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); see also *Pafford v. Sec'y of Health & Hum. Servs.,* 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner who satisfies this burden is entitled to compensation unless respondent can prove, by a preponderance of the evidence, that the vaccinee's injury is due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B).

To receive compensation through the Program, petitioner must prove either (1) that [he] suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that she received, or (2) that he suffered an injury that was actually caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); *Capizzano v. Sec'y of Health & Hum. Servs.,* 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). Because petitioner does not allege that he suffered a Table Injury, he must prove that a vaccine he received caused his injury. To do so, he must establish, by preponderant evidence: (1) a medical theory causally connecting the vaccine and his injury ("*Althen* Prong One"); (2) a logical sequence of cause and effect showing that the vaccine was the reason for her injury ("*Althen* Prong Two"); and (3) a showing of a proximate temporal relationship between the vaccine and her injury ("*Althen* Prong Three"). § 13(a)(1); *Althen*, 418 F.3d at 1278.

The causation theory must relate to the injury alleged. The petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be "legally probable, not medically or scientifically certain." *Knudsen v. Sec'y of Health & Hum. Servs*., 35 F.3d 543, 548-49 (Fed. Cir. 1994). Recently, in *Kottenstette,* the Federal Circuit reiterated that proof of causation does not "require identification and proof of specific biological mechanisms[.]" *Kottenstette v. Sec'y of Health & Hum. Servs.,* --Fed.Appx.—(Fed. Cir. June 15, 2021) (citing *Knudsen v. Sec'y of Health & Hum. Servs.,* 35 F.3d 543, 549 (Fed. Cir. 1994). Causation "can be found in vaccine cases….without detailed medical and scientific exposition of the biological mechanisms." *Knudsen,* 35 F.3d 543, 548-49 (Fed. Cir. 1994). It is not necessary for a petitioner to point to conclusive evidence in the medical literature linking a vaccine to the petitioner's injury, as long as the petitioner can show by a preponderance of evidence that there is a causal relationship between the vaccine and the injury, whatever the details of the mechanism may be. *Moberly v. Sec'y of Health & Hum. Servs.,* 592 F.3d 1315, 1325 (Fed. Cir. 2010).

Petitioner cannot establish entitlement to compensation based solely on his assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In determining whether petitioner is entitled to compensation, the special master shall consider all material in the record, including "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation." § 13(b)(1)(A). The undersigned must weigh the submitted evidence and the testimony of the parties' proffered experts and rule in petitioner's favor when the evidence weighs in his favor. *See Moberly,* 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence."); *Althen*, 418 F.3d at 1280 (noting that "close calls" are resolved in petitioner's favor).

In Vaccine Act cases, expert testimony may be evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc*., 509 U.S. 579, 594-96 (1993); *see also Cedillo,* 617 F.3d at 1339 (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). In Vaccine Program cases, the *Daubert* analysis has been used in the weighing of the scientific evidence actually proffered and heard rather than as a tool for the pre-trial exclusion of expert testimony. *Davis v. Sec'y of Health & Hum. Servs*., 94 Fed. Cl. 53, 66–67 (Fed. Cl. 2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"), *aff'd*, 420 F. App'x 923 (Fed. Cir. 2011). The flexible use of the *Daubert* factors to determine the persuasiveness and/or reliability of expert testimony in Vaccine Program cases has routinely been upheld. *See, e.g*., *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 742–45 (2009). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly,* 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

Close calls regarding causation must be resolved in favor of the petitioner. *Althen*, 418 F.3d at 1280 (holding that Congress created a system in which "close calls regarding causation are resolved in favor of injured claimants"); *Knudsen*, 35 F.3d at 551 ("If the evidence (on alternative cause) is seen in equipoise, then the government has failed in its burden of persuasion and compensation must be awarded.").

V. Finding of Fact

a. Parties' arguments regarding onset

In this case, the main issue of fact to be resolved prior to the consideration of causation is the onset of petitioner's pain and shoulder dysfunction.

Respondent argued that the onset of petitioner's shoulder pain was much later than 48-hours after vaccination and therefore, not associated with the flu vaccine petitioner received on October 20, 2015. Resp. Brief at 13-14. Specifically, respondent argued that the first report of right shoulder pain occurred on January 12, 2016. *Id.* at 13. Respondent also argued that petitioner had two intervening appointments between October 20, 2015 (date of vaccination) and January 20, 2016, where petitioner did not report right shoulder pain. *Id.* at 13; *see also* Pet. Ex. 2 at 136, 138. Respondent's expert, Dr. Cagle argued that petitioner did not complain of right shoulder pain at these two appointments and notes that at the November 10, 2015 appointment, petitioner had his blood pressure checked on his right arm. Resp. Ex. J at 4. Dr. Cagle opined that getting the cuff on petitioner's right arm would have required some manipulation of the arm, which would have caused pain, but there was no notation of petitioner experiencing right shoulder pain. Tr. 246.

Petitioner asserted that his should pain began the same day he received the intradermal flu vaccine, October 20, 2015, and had begun to be sore or painful by lunchtime on the day that he received the vaccination. Pet. Post-Hearing Brief at 12.

b. Discussion and conclusion regarding the onset of petitioner's right shoulder pain and dysfunction

Petitioner has demonstrated by preponderant evidence that his right shoulder symptoms began within forty-eight hours of receiving the intradermal flu vaccine on October 20, 2015. More specifically, petitioner provided preponderant evidence that soreness leading to pain began within an hour of the vaccination.

The testimony from the fact witnesses and petitioner himself demonstrated that petitioner experienced soreness the same day he received the vaccine and that the soreness transformed into pain over the next two days, resulting in decreased shoulder mobility. Petitioner testified credibly that his right arm felt sore immediately after he received the intradermal flu vaccine. Tr. 8. Petitioner stated that on the day he received the flu vaccine, he went to the regular family lunch with his fiancée, sisters and mother. Tr. 8. He testified that he told his family that day that his arm was "awfully sore." *Id.* He stated that the soreness developed into pain after two days and it kept getting worse. Tr. 14. Petitioner testified that the soreness transitioned to pain "real

quick." Tr. 33. He explained that the medical assistant administering the vaccination was standing while he was sitting. Tr. 13. He said that the medical assistant told him that she wasn't too experienced at giving injections. Tr. 15. Further, he demonstrated that the vaccine was administered high on his right shoulder, close to the acromion bone. Tr. 16. Petitioner also stated that the vaccine caused a red mark "high on the right shoulder" and the injection site "took a very long time to heal." Tr. 16. Additionally, petitioner testified that he had not experienced any shoulder pain prior to the vaccination. Tr. 16.

Petitioner also testified that he called his primary care physician, Dr. Sutton, either two or three days after the vaccination and reported that his arm was sore. Tr. 9. He stated that Dr. Sutton's office called him back and left a message telling him to take Tylenol for two to three weeks. Ms. Beatty also heard the voice message from a woman in Dr. Sutton's office telling him to take Tylenol for the pain. Tr. 44. Petitioner testified that the pain he experienced became continuous and "never went away." Tr. 26. He stated that between the period of the vaccination to his first appointment in January 20, 2016, he had some difficulty moving his arm, and in particular, had difficulty lifting items. Tr. 24.

Petitioner's testimony was corroborated by the testimony of Ms. Beatty, Ms. Prough, Ms. Steele and Ms. Mills that his shoulder pain began the same day he received the intradermal flu vaccination.

Ms. Beatty explained that the day he received the vaccine, petitioner was complaining that his arm was sore at the injection site. Tr. 41-42. She also confirmed that after approximately two days of soreness, his right shoulder became painful. Tr. 42. Ms. Beatty stated that a couple of days after he received the vaccination, he called the doctor's office to complain about his shoulder pain and Dr. Sutton's office called and left a message for petitioner to take Tylenol for the pain. Tr. 43-44. She stated that petitioner's shoulder pain got progressively worse. Tr. 45. Additionally, Ms. Beatty testified that she had seen the mark on petitioner's shoulder where the vaccine was given. Tr. 46. She stated that it was on the "upper part of his shoulder, pretty high up on his arm." *Id.* When asked to demonstrate where on the shoulder the mark was, she stated that it was just below the acromion. Tr. 47.

Ms. Beatty also testified that the family lunch occurred as usual on the day petitioner received the vaccination. Tr. 51. She stated that during the lunch on October 20, 2015, petitioner told his family that his arm was sore from the flu shot. *Id.* She also explained that at lunch the next day, petitioner again told his family his arm was sore from the flu shot. *Id.*

Petitioner's sisters, Ms. Prough, Ms. Steele, and Ms. Mills also testified that petitioner reported that his arm was sore at lunch on October, 20, 2015. Tr. 56, 65, 71. More specifically, Ms. Steele testified that at the family lunch, petitioner stated that "my arm just really hurts from that flu shot." Tr. 65. Ms. Steele also testified that petitioner showed her where he had received the injection and she described it as, "on the upper arm…above the fatty tissue on the arm." Tr. 65-66. She also stated that there was a mark where petitioner had received the injection. Tr. 66. Ms. Mills also testified that the day petitioner received the flu vaccine, petitioner reported at the daily lunch that his arm was really sore and "it hurt really bad." Tr. 71. Ms. Mills explained that she never saw the exact location of the injection, she explained that petitioner would be touching

his upper arm, near his shoulder. Tr. 73. She testified that during the lunches, her mother would ask petitioner about his arm and petitioner would "tell us every day that it hurt bad." Tr. 72.

Ms. Beatty, Ms. Mills, Ms. Steele, and Ms. Prough, all of whom were present at the family lunch on October 20, 2015, consistently testified that petitioner was experiencing soreness in his right shoulder during lunch, which occurred shortly after his doctor's appointment. Additionally, they all testified that petitioner continued to experience pain and discomfort in his right shoulder and would express that he was having pain at the daily lunches. Further, they testified that petitioner had no history of right shoulder pain or dysfunction until after the vaccination. I found their testimony to be consistent and credible in describing the onset of petitioner's soreness and pain at the injection site as well as in describing his complaints of ongoing shoulder pain, its worsening and its effect on his ability to use the arm.

The testimony by the witnesses is consistent with the medical records, in which petitioner consistently related the onset of his shoulder pain and dysfunction to the vaccination on October 20, 2015. On January 12, 2016, Ms. Beatty called Dr. Sutton's office to report that petitioner was experiencing right shoulder pain. Pet. Ex. 7 at 10. Specifically, the note states, "Pt's girlfriend, (Lori) on contact list, called stating patient was given flu shot in October and patient still has mark where injection was given, in addition he is experiencing numbness in finger and shoulder pain. States thinks it could be from the injection." *Id.* Then on January 20, 2016, when petitioner was seen by Dr. Sutton, the nurse's note states, "Acute appt today for pain in right shoulder *since flu shot 10/2015."* Pet. Ex. 2 at 141. Then the note states that, "petitioner states this began about two weeks after the intradermal injection-no known injury to shoulder-pt states difficulty moving shoulder and arm." *Id.* When petitioner had his initial physical therapy evaluation, petitioner reported that he "got a flu shot in October, and feels that the shot has contributed to his symptoms." Pet. Ex. 3 at 20. Even though the appointment note also states that petitioner reported his pain began in early November, petitioner testified that his pain had become much worse by early November and had been continuous from the time he received the shot to November. Tr. 25-26.

Later, when petitioner was first evaluated by Dr. Demuth on March 15, 2016, the nurse's note stated, "Established patient referred by Dr. Sutton, MD for right shoulder pain which developed after receiving his flu vaccine 10-20-2015." Pet. Ex. 2 at 143. Under "History of Present Illness" at the same appointment, Dr. Demuth wrote, "The patient is having some [pain] with his right shoulder for a number of months. He relates that in the general timeframe to a flu shot…." *Id.* Again, this record demonstrates that petitioner related the beginning of his shoulder pain and dysfunction to the flu shot he received on October 20, 2015.

Respondent's argument that petitioner's shoulder pain began at a later time because he failed to report it at the medical appointments on November 10, 2015 and January 6, 2016 is unpersuasive. As the Federal Circuit articulated in *Kirby,* there is no "presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). Following *Kirby,* a special master must consider the context of a medical encounter before concluding that it constitutes evidence regarding the absence of a condition. *Hanna v. Sec'y of Health & Hum. Servs.,* No. 18-1455V, 2021 WL 3486248, at *14 (Fed. Cl. Spec. Mstr. July 15, 2021). Here, petitioner's November

10, 2015 appointment was for an "acute visit for elevated blood pressure at home." Pet. Ex. 2 at 136. He had his blood pressure checked in both his right and left arm. *Id.* At the January 6, 2016 appointment, petitioner came in for a medication re-check and to have his blood pressure checked. *Id.* at 138. At this appointment his blood pressure was taken from his left arm. *Id.* at 139. Further, a delay in seeking treatment or a failure to report symptoms to a physician during an appointment for other issues is not necessarily dispositive of whether a petitioner's symptoms began within the appropriate timeframe. *See Stephens v. Sec'y of Health & Human Servs.,* No. 19-1685V, 2021 WL 482355 (Fed. Cl. Spec. Mstr. Sept. 15, 2021) (finding that petitioner's onset of pain was within the appropriate timeframe with a 70-day delay in seeking treatment for a SIRVA); *McGee v. Sec'y of Health & Human Servs.,* No. 18-1778V, 2021 WL 6059588 (Fed. Cl. Spec. Mstr. Nov. 30, 2021) (finding onset of shoulder pain within the appropriate timeframe with a five-month delay in treatment); *Desai v. Sec'y of Health & Human Servs.,* No. 14-811V, 2020 WL 4919777 (Fed. Cl. Spec. Mstr. July 30, 2020) (finding petitioner had established onset of pain within 48 hours of vaccination even though she delayed treatment for three months); *see also Forman-Franco v. Sec'y of Health & Hum. Servs.,* No. 15-1479V, 2018 WL 1835203 (Fed. Cl. Spec. Mstr. Feb. 21, 2018); *Tenneson v. Sec'y of Health & Hum. Servs.,* No 16-1664V, 2018 WL 3083140 (Fed. Cl. Spec. Mstr. Mar. 30, 2018), *mot. rev. denied* 142 Fed. Cl. 329 (2019); *Gurney v. Sec'y of Health & Hum. Servs.,* No 17-481V, 2019 WL 2298790 (Fed. Cl. Mar. 19, 2019). In this case, it is also important to note that the petitioner testified that he called Dr. Sutton's office within a couple days of receiving the vaccination to complain about pain and the doctor's office told him to take Tylenol for two or three weeks for the pain.

Additionally, petitioner's expert, Dr. Srikumaran testified that it was his experience that when people have musculoskeletal pain, it is not uncommon for them to wait weeks or months to seek medical care and evaluation. Tr. 122. In his first report, he wrote, "The vast majority of patients do not have their pain evaluated within 48 hours." Pet. Ex. 25 at 6. He explained that most people are hopeful things will improve with time and basic measures and try several other over-the-counter remedies for many weeks or months. *Id.*; Tr. 122. He cited to an article by *Shi Qiuling et al.*, which stated, "Some people do not seek medical attention, even when moderate or severe pain is present. Beyond factors related to the health care system itself, a variety of potential obstacles may be responsible for the underutilization of medical treatment for pain in the general population." *Id.* at 6; Pet. Ex. 34 at 2.[17] Dr. Srikumaran stated that he found that it was his experience as a practicing surgeon that there are many barriers to treatment. Pet. Ex. 25 at 6. He testified that "so many things that affect access to their pain evaluated and managed…really it depends on a host of factors of this individual, their social situation, their insurance situation, how bad his pain is, how well they are managing with it, how important their job is, or their ability to get an appointment, or finances." Tr. 122. Dr. Srikumaran testified that it was his opinion that petitioner being told by his doctor to take Tylenol "days after receiving the vaccine," would have given the petitioner reassurance "to allow more time to pass even before seeking further follow-up care." Tr. 123.

The testimony provided by witnesses was consistent with one another and consistent with the medical records that the onset of petitioner's pain began within 48 hours of receiving the intradermal flu vaccination on October 20, 2015. Additionally, the medical records also demonstrate that petitioner consistently related the onset of his pain to the flu vaccine he

[17] Shi, Q., et al., *People in Pain: How Do They Seek Relief?* 8 The Journal of Pain, 624-636 (2007). [Pet. Ex. 34].

received in October. Therefore, I find that petitioner has provided preponderant evidence that the onset of his right shoulder pain and dysfunction began within 48 hours of receiving the influenza vaccine on October 20, 2015.

VI. Causation Analysis

a. *Althen* prong one

Under *Althen* prong one, the causation theory must relate to the injury alleged. The theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen*, 35 F.3d at 548. It must only be "legally probable, not medically or scientifically certain." *Id.* at 549. However, the theory still must be based on a "sound and reliable medical or scientific explanation." *Id.* at 548. The Federal Circuit explained in *Althen* that "while [that petitioner's claim] involves the possible link between [tetanus toxoid] vaccination and central nervous system injury, *a sequence hitherto unproven in medicine*, the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field *bereft of complete and direct proof of how vaccines affect the human body." Althen,* 418 F.3d at 1280 (emphasis added).

1. Background on the intradermal flu vaccination

According to the Fluzone Intradermal Quadrivalent package insert ("package insert"), the intradermal quadrivalent flu vaccine is intended for adults 18 to 64 years of age and contains 0.1 ml of fluid. Resp. Ex. F. The insert notes that the "preferred site of injection is the skin in the region of the deltoid." *Id.* at 2. The microneedle injection system, pictured below, uses a hollow microneedle that "penetrates 1.5 mm into the skin from the outer skin surface." Resp. Ex. A at 8. The vaccine administrator is to hold the device perpendicular to the skin, between the thumb and middle finger, keeping the index finger free to compress the plunger. Resp. Ex. F at 3-4. The packet insert explains, "Because the vaccine is injected into the skin, a wheal (superficial bump) and/or redness may be visible at the injection site. *Id.* In a controlled safety and immunogenicity study of the Fluzone Intradermal Quadrivalent vaccine, 53% of recipients reported pain at the injection site within seven days of vaccination, compared to 48% of those who received an intradermal trivalent flu vaccine. *Id.* at 8. Additionally, 11% of those that reported pain at the injection site who received the Fluzone Intradermal Quadrivalent characterized the pain as having "some or significant interference with daily activities." *Id.* at 9. This was compared to 9% who received the intradermal trivalent flu vaccine. *Id.* Further, 19% of participants who received the Fluzone Intradermal Quadrivalent vaccine reported swelling at the injection site, compared to 14% who received the other intradermal vaccinations. *Id.*

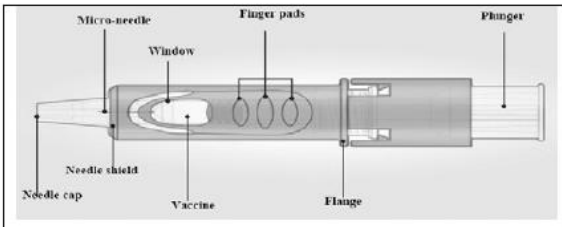


Figure 1. Diagram of micro-injector used to administer Fluzone Intradermal Quadrivalent vaccine. (4)

Figure 2. Typical flu shots are intramuscular, which means they go through the skin, a layer of fat, and then the muscle. Intradermal vaccines are injected into the skin through a small, ultra-thin needle (5).

Resp. Ex. A at 8.

Respondent also submitted the Fluzone Intradermal Fact Sheet, which gave an overview of the intradermal flu vaccine and provided information about the clinical trials. Resp. Ex. H. The fact sheet stated, "Fluzone Intradermal vaccine is safe, with a comparable systemic reaction profile to the intramuscular vaccine…..The injection site reactions were more frequent with participants given the intradermal vaccine compared to the intramuscular vaccine, with the exception of pain, which was similar." *Id.* at 2.

The *Lambert et al*. article, submitted by the respondent, explained that the skin was recognized "as a potentially excellent site for vaccination," because, in part, it "has both cellular and humoral immune system components." Resp. Ex. E at 4. Further, the article noted that, "intradermal influenza vaccination in elderly subjects (0.1 ml dose) induced a humoral immune response superior to the [intramuscular] control against all three strains." *Id.* at 3. The Laurent et al. article explained, "Intradermal immunization using a 1.5 mm microjet injection system has shown that it is possible to reduce vaccine dose while maintaining humoral immune responses comparable to those obtained via the standard intramuscular route." Pet. Ex. 22 at 6.

2. Discussion and Conclusion of *Althen* prong one

Respondent's experts asserted that the 1.5 mm needle used for the intradermal flu vaccination itself could not directly penetrate the subdeltoid/subacromial bursa, and therefore, could not have caused petitioner's right shoulder pain and dysfunction. Tr. 204, 226; Resp. Ex. J at 6. Instead, they argued that any pain experienced by petitioner post-vaccination was the result of his previously asymptomatic rotator cuff tear, becoming symptomatic, and that it was merely coincidental that his shoulder pain and dysfunction began so close in time to the vaccination. *See* Resp. Ex. I at 4; Resp. Ex. J at 4; Tr. 195, 237-39. The core of respondent's argument is that the intradermal vaccine antigen is contained to the dermis layer and any transient inflammation at the vaccination site was unrelated to initiating petitioner's shoulder bursitis and rotator cuff pathology becoming painful.

Petitioner, through his three experts, demonstrated that the intradermal vaccination he received, initiated an immune-mediated inflammatory response in and around the structures of his right shoulder, sufficient to induce pain and reduced mobility. Pet. Ex. 18 at 2; Pet. Ex. 25 at 7; Tr. 112.

Petitioner's experts, Drs. Srikumaran and Bodor, concluded that petitioner suffered shoulder pain and dysfunction following the receipt of the intradermal flu vaccination. Pet. Ex. 18 at 2; Pet. Ex. 25 at 7. Dr. Srikumaran explained that, despite petitioner receiving an intradermal vaccination, the evidence demonstrates that petitioner met the four elements required to demonstrate a shoulder injury related to vaccine administration ("SIRVA"). Pet. Ex. 25 at 6-7; Tr. 90. The theory of a SIRVA, as discussed by Dr. Bodor in his article and the *Atanasoff* article, is that the antigenic material of a vaccine is injected into or near the subacromial bursa, causing a significant inflammatory response, leading to pain and shoulder dysfunction. Pet. Ex. 14 at 1; Pet. Ex. 25 at 9; Tr. 89-90. Dr. Bodor explained that the pain, which is caused by inflammation, varies between individuals and "the degree of inflammation varies from mild to severe depending on an individual's previous immune exposures and other factors." Pet. 18 at 1.

Dr. Srikumaran explained that common characteristics of a post-vaccine shoulder injury are that they present as bursitis or tendonitis of the shoulder, patients note immediate or a "tight time correlation to the time of their vaccination," and pain in the lateral aspect of the shoulder. Tr. 89-90. He noted that many patients with post-vaccination shoulder injuries complain of pain at night in the shoulder, difficulty using the shoulder away from their body, decreased range of motion over time, and progressive symptoms. Tr. 90. Dr. Srikumaran and Dr. Bodor both agreed that petitioner suffered a post-vaccination shoulder injury, as demonstrated by petitioner's onset of pain and dysfunction within forty-eight hours of the vaccination, petitioner did not have any pre-existing shoulder pain or mobility issues in his right shoulder, and he was diagnosed with bursitis after months of shoulder pain following the flu vaccine he received on October 20, 2015.

Petitioner's experts credibly explained that the location of vaccination petitioner received in his right shoulder made it possible for the 1.5 mm needle to be injected further than the intended dermal layer of skin, penetrating his deltoid muscle. Petitioner testified that he received the intradermal flu vaccination high on his right shoulder. Tr. 15. First, Dr. Shaer, citing to the *Laurent* article, explained that the skin thickness of individuals between 51-70 years of age, varied from 1.98 mm to 2.28 mm at the deltoid, which makes it "possible for a misplaced injection, even when administered with a 1.5 mm, to reach structures that can respond with severe inflammation." Pet. Ex. 17 at 2; Pet. Ex. 22 at 4. Dr. Srikumaran explained that the area where petitioner received his flu vaccination was at a point where the skin and muscle are the thinnest. Tr. 117. When Dr. Bodor reviewed the ultrasound of petitioner's shoulder during the hearing, he noted that the depth of petitioner's skin at the location of where he said the vaccination was given, was measured at approximately 2.1 mm. Tr. 141; *see also* Pet. Ex. 37 at 1. Dr. Bodor stated that it is "biologically plausible for when a Fluzone micro-injector is applied firmly against the skin, and the skin is compressed, the 1.5 mm Fluzone needle could penetrate into the deltoid muscle." Pet. Ex. 18 at 1. Dr. Bodor explained that the ultrasound of petitioner's right shoulder demonstrated that his deltoid muscle at the high point in the shoulder where the injection occurred was 2.1 mm below the skin and that "if the needle is compressed, the skin will compress by 50 percent….we can expect that the skin thickness can be reduced down to 1 mm, and you can definitely penetrate that deltoid muscle." Tr. 139. Dr. Srikumaran further explained that "in the area of the shoulder, the skin is compressible, the subcutaneous fat is very compressible and even the muscle is compressible. Tr. 97. Agreeing with Dr. Bodor's

statements, Dr. Srikumaran opined that "it is quite feasible, and even likely in…some…cases that some injectors may [be] inadvertently pushed harder than is recommended by the manufacturer. Pet. Ex. 25 at 8; Tr. 97.

Respondent's expert, Dr. Cagle also conceded that the microinjector could have reached the deltoid muscle. In his report, Dr. Cagle conceded that a 1.5 mm needle could be pressed firmly and penetrate an additional 0.6 mm to reach the deltoid muscle, although he argued that there was a layer of fatty tissue separating the skin and the muscle which would make it unlikely. Resp. Ex. J at 3-4. During the hearing, he again stated that "it seems unlikely but theoretically possible," that the 1.5 mm needle could be pressed and "get at least the tip of [the deltoid muscle]," through the skin. Tr. 239-40.

Both Drs. Srikumaran and Bodor credibly explained that it is not simply the injection high into the shoulder that causes the pain, but the "initiation of inflammation," directly related to the vaccine antigen being delivered near the bursa, which results in pain in previously asymptomatic degenerative shoulder conditions. Pet. Ex. 18 at 2; Pet. Ex. 25 at 8. Dr. Srikumaran conceded that the needle was unlikely to reach deeper structures in the shoulder, such as the rotator cuff tendon, but asserted that it was the inflammation initiated in petitioner's deltoid that spread to other shoulder structures. Tr. 117. Dr. Srikumaran testified that the structures of the shoulder "are quite contiguous and flow from one to another." Tr. 112. He explained, consistent with the medical literature, that the "subacromial bursa connects to the subdeltoid area, all the way to the joint." *Id.* He stated that the area closest to the acromial bone "appears to have the highest risk" of someone developing a shoulder injury after vaccination. Tr. 114. This is because both the skin and the deltoid muscle are thinnest at the higher part of the shoulder and the subdeltoid bursa is also closer to the acromion. *Id.* at 112-14. Dr. Srikumran opined that an "inflammatory response does not restrict itself to areas as small as millimeters or centimeters." Pet. Ex. 25 at 8; Tr. 100. Instead, he argued that the inflammation is well known to be capable of spreading to adjacent structures, as commonly occurs after a bee or wasp sting. Pet. Ex. 25 at 8; Tr. 101. Dr. Srikumaran testified that when there is wear and tear, such as a rotator cuff tear, it creates pathways for inflammation, and as a result a person's response to an antigen, can spread through the structures and cause inflammation in the nearby structures. Tr. 112. Dr. Srikumaran summarized, "the needle need not directly touch the tendon or bursa, rather the inflammatory response likely included these areas, as they are in close proximity," causing pain. Pet. Ex. 25 at 9; Tr. 112. Dr. Bodor agreed with Dr. Srikumaran that inflammation in the deltoid muscle would not necessarily be confined to the deltoid muscle, but spread to surrounding structures, such as the bursa, resulting in bursitis. Tr. 144.

Respondent's experts' opinion that petitioner's pain and shoulder dysfunction beginning shortly after the flu shot was caused by the pre-existing rotator cuff pathology, suddenly becoming painful without relationship to the vaccine is not credible. None of the experts asserted that petitioner's underlying rotator cuff pathology was caused by the intradermal flu vaccination. Additionally, all the experts agreed that petitioner's previously asymptomatic rotator cuff tear became symptomatic at some point after the vaccination. *See* Pet. Ex. 25 at 7; Resp. Ex. A at 8; Resp. Ex. J at 4; Tr. 146, 195. However, respondent's experts, argued that something other than the vaccination triggered petitioner's shoulder pathology symptoms, without identifying a possible other inciting event in the medical records. Tr. 302. Dr.

Schroeder acknowledged that petitioner may have experienced a local reaction to the vaccination, but "then two weeks later and totally unrelated, petitioner suffered symptoms from a tear in the rotator cuff." Tr. 195. Dr. Cagle argued that petitioner's rotator cuff tears becoming symptomatic was the natural progression of rotator cuff tears. Tr. 239; Resp. Ex. J at 4.

Petitioner's experts opined that petitioner's shoulder pathology becoming symptomatic after the vaccination was consistent with an immune-mediated inflammatory reaction. Drs. Srikumaran and Bodor observed that petitioner did not experience any symptoms related to his rotator cuff tears prior to the vaccination. Pet. Ex. 25 at 7; Tr. 146. Dr. Srikumaran explained that shoulder injuries related to vaccine administration can occur in prone individuals through inflammation who have been previously sensitized through either prior natural infections or prior vaccinations, making the "immune-mediated inflammatory response more significant in those individuals." Tr. 101. He stated that the initiation of inflammation, initiates the pain in previously long standing silent, chronic, degenerative conditions. Pet. Ex. 25 at 8. Dr. Srikumaran's opinion is supported by the medical literature submitted by both parties. The *Atanasoff* article explains, "Although shoulder dysfunction due to mechanical or overuse is always a diagnostic consideration, the rapid onset of pain with limited range of motion following vaccination….is consistent with a robust and prolonged immune response with already-sensitized shoulder structures following injection of antigenic substance." Pet. Ex. 21 at 3. The authors theorized that some of the MRI findings in their patients, such as rotator cuff tears, "may have been present prior to vaccination and became symptomatic as a result of vaccination-associated synovial inflammation." *Id.* at 3. The *Cross* article submitted by respondent, also supports petitioner's theory. The article states that, "Shoulder injury from vaccination is greater than would be expected from a simple needle trauma. An immune-mediated reaction to the adjuvant, antigenic or non-antigenic components of the vaccine have been implicated. A robust and prolonged reaction may be the response of a sensitized population who have antigenic exposure from previous vaccination or previous infection." Resp. Ex. EE at 4. Given that petitioner was 58 at the time he received the intradermal vaccination, and his medical records indicate that he had received a flu vaccine in March of 2015, it is more than likely that petitioner experienced a robust immune-mediated inflammatory response to the intradermal vaccine, resulting in pain and shoulder dysfunction.

Petitioner has presented a reputable scientific theory based on a sound and reliable medical explanation demonstrating the intradermal flu vaccine can cause shoulder pain and dysfunction, thus satisfying *Althen* prong one.

b. *Althen* prong two

Under *Althen* prong two, petitioner must prove "a logical sequence of cause and effect showing that the vaccination was the reason for [his] injury." *Althen*, 418 F.3d at 1278. This prong is sometimes referred to as the "did it cause" test; i.e. in this particular case, did the vaccine(s) cause the alleged injury. *Broekelschen*, 618 F. 3d at 1345 ("Because causation is relative to the injury, a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case"). Temporal association alone is not evidence of causation. *See Grant v. Sec'y of Health & Hum. Servs.,* 9556 F.2d 1144, 1148 (Fed. Cir. 1992). This sequence of cause and effect is usually supported by facts derived from petitioner's medical

records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant*, 956 F.2d at 1148. Treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury. *Paluck v. Sec'y of Health & Hum. Servs.,* 786 F.3d 1373, 1385 (Fed. Cir. 2015) (quoting *Andreu*, 569 F.3d 1375).

Petitioner's experts opined that the flu vaccine caused an immune-mediated inflammatory response which resulted in pain and decreased shoulder mobility. Pet. Ex. 17; Pet. Ex. 25; The inflammation caused a pre-existing asymptomatic shoulder tear to become symptomatic and painful. Tr. 101, 147. Drs. Srikumaran and Dr. Bodor stated that the flu vaccination did not cause the rotator cuff tears identified on petitioner's MRI but was the cause of it becoming symptomatic. Tr. 99.

Dr. Schroeder testified that the intradermal vaccine would cause an inflammatory response at the site of the injection that could result in local pain, swelling, redness and a "mark that will last for a while." Tr. 175, 178. He explained that the mark on petitioner's arm after the intradermal vaccine was consistent with a reaction to an intradermal vaccine. Tr. 185. However, he argued that the local inflammatory reaction would not spread to the petitioner's subacromial bursa. Tr. 178. He also agreed that it was likely that petitioner had a pre-existing rotator cuff tear that was asymptomatic, but he stated that in most cases of asymptomatic pre-existing rotator cuff tears, "there isn't a known inciting event, it just starts happening." Tr. 202. When asked to provide an opinion about how petitioner's initial soreness from the vaccine turned into significant pain, Dr. Schroeder stated, "I can attribute what happened within the first 48 hours to the vaccination quite easily. As to what happened after that, it's very unusual-I don't see how the local inflammation, which would have resulted from the vaccination, would have extended to the deltoid muscle." Tr. 220.

Respondent's orthopedic expert, Dr. Cagle, agreed with the other experts that the vaccine did not cause the rotator cuff tears identified on petitioner's MRI. Resp. Ex. J at 3; Tr. 230. Dr. Cagle asserted that if petitioner had inflammation in the deltoid "and/or secondarily the bursa, you would expect an individual to have…acute pain with their shoulder," and the medical records did not demonstrate that petitioner had any pain when having his blood pressure taken on November 10, 2015. Tr. 226-27. He also argued that the steroid injection petitioner received, an anti-inflammatory, would have provided some relief if petitioner had an inflammatory process that resulted in pain and shoulder dysfunction." Tr. 229. Dr. Cagle explained that an MRI would show inflammation as a signal change, but that petitioner's MRI did not show any inflammation "in the belly of the deltoid muscle." Tr. 243-44. He testified that even if the MRI was taken three months after the initial onset of symptoms, the inflammation would still be demonstrated on the MRI. Tr. 244. Dr. Cagle asserted that petitioner's pre-existing shoulder pathology, the partial rotator cuff tears became symptomatic, which was the cause of petitioner's right shoulder pain and dysfunction. Tr. 255. He stated that a person does not need to experience trauma for a previously asymptomatic rotator cuff tear to become painful. *Id.* He testified that it is unknown why previously asymptomatic rotator cuff tears have an acute onset of pain. Tr. 256.

Prior to receiving the vaccine, petitioner did not experience any right shoulder pain or dysfunction. Petitioner received the intradermal flu vaccination on October 20, 2015. Pet. Ex 1. Petitioner testified that he was sitting and the medial assistant, who administered the shot, was standing. Tr. 15. He also testified that it was given high up on his arm. *Id.* The same day, petitioner reported that he was having pain in his right shoulder to his sisters and fiancée at lunch. Tr. 8. He testified that he called the doctor's office and they instructed him to take Tylenol for a few weeks and call back if his pain continued. *Id.* at 9. On January 12, 2016, Ms. Beatty called Dr. Sutton and explained that petitioner still had a mark on his right shoulder where the injection was given, and petitioner was experiencing shoulder pain. Pet. Ex. 7 at 10. It was recommended that petitioner apply heat and take Tylenol for his shoulder. *Id.*

On January 20, 2016, petitioner had an appointment with Dr. Sutton for right shoulder pain. Pet. Ex. 2 at 141. At this appointment, petitioner again relates the pain in his right shoulder to the flu vaccination he received on October 20, 2015. *Id.* The physical exam revealed that petitioner had "pain with both active and passive abduction" and he was unable to abduct his shoulder beyond 70 degrees without discomfort. *Id.* Additionally, a trigger point was identified over his right posterior rotator cuff in the subacromial space." *Id.* Petitioner received a shot of Depo-Medrol and Xylocaine into his subacromial space of his right shoulder. *Id.* Petitioner called Dr. Sutton's office and explained that he had no relief from the cortisone shot. Pet. Ex. 7 at 8.

After attending physical therapy and not having any improvement, petitioner had an appointment with orthopedic surgeon Dr. William Demuth. Pet. Ex. 2 at 143. At this appointment petitioner again related the onset of his pain to his flu vaccination, but Dr. Demuth dismissed petitioner's assertion. Dr. Demuth noted that petitioner had discomfort elevating his arm over 90 degrees and had subacromial space pain on internal and external rotation. *Id.* Dr. Demuth diagnosed petitioner with bursitis of the right shoulder and ordered an MRI of petitioner's right shoulder. *Id.* at 143-44.

The MRI taken on March 16, 2016, showed mild T1 and T2 signal within the supraspinatus and infraspinatus tendons, a focal fluid signal intensity in the anterior aspect of the supraspinatus tendon that was compatible with a focal high-grade tear, a partial tear of the subscapularis tendon, and mild edema in the subacromial/subdeltoid bursa was identified. Pet. Ex. 2 at 365-66. After reviewing the MRI on March 22, 2016, Dr. Demuth recommended that petitioner undergo a rotator cuff repair. *Id.* at 149. On May 17, 2016, petitioner underwent a right shoulder rotator cuff repair with acromioplasty. Pet. Ex. 2 at 382.

Petitioner's onset of pain, shoulder dysfunction and treatment course are consistent with the medical literature cited by his experts. The *Atanasoff* article explained that all the patients in the cases identified experienced shoulder pain and nearly half expressed concern that the vaccine was administered "too-high." Pet. Ex. 21 at 2. Additionally, the authors also noted that MRI findings included bursitis, fluid in the bursa, tendonitis and rotator cuff tears, although they posited that some rotator cuff tears have pre-dated the vaccination and became symptomatic as a result of associated synovial inflammation. *Id.* at 2-3. Further, the study by *Hesse et al.* article, examined 476 shoulder pain and dysfunction cases within the VICP to identify common

characteristics. Pet. Ex. 31.[18] Consistent with the *Atanasoff* article, the *Hesse* study found that 36% of petitioners reported injections "too high" in their arm and 32.6% of cases resulted in surgery. *Id.* at 1. The authors found that of the surgical cases, 29.7% of patients underwent rotator cuff repair. *Id.* at 6. Additionally, MRI findings of conceded cases included partial rotator cuff tears (34.9%) bursitis (34.4%), and complete rotator cuff tears (9.4%). *Id.* at 5.

The petitioner testified that the vaccine was given high on his arm by the medical assistant. Tr. 15. Additionally, he explained that he was sitting, while she was standing. *Id.* Petitioner also stated that the medical assistant explained she was inexperienced at giving injections. Tr. 15. As explained in the *Atanasoff* article "while patients are often seated for vaccinations, the standing position of the provider administering the injection may also contribute to injecting inadvertently high into the deltoid." Pet. Ex. 21 at 4. Further, at the time the petitioner received the vaccination, the microinjector system was relatively new and had only been first authorized for use in the U.S. for the 2011-2012 flu season.[19] Given that the injection was given high on petitioner's shoulder where the skin is the thinnest, as demonstrated by the ultrasound, petitioner was seated while the vaccine was administered, and the microinjector system was relatively new technology, it seems more likely that the vaccine was mis-administered past the intended target of the skin and into his deltoid, resulting in prolonged inflammation.

Finally, respondent's experts' opinions that petitioner's shoulder pain and dysfunction was caused by his underlying shoulder pathology is based on a disbelief that the onset of petitioner's pain could be related to the vaccination. Dr. Schroeder stated, "I think that he had a local reaction to the vaccination, which is well within the bounds of what I expect in that type of vaccination and that he two weeks later, and totally unrelated [to the vaccination], he suffered symptoms from a tear in the rotator cuff that he may…have had before." Tr. 195. Dr. Schroeder testified that, "Patients often have acute onset of pain in rotator cuff injuries…I think that for the most cases of acute pain from rotator cuff, there isn't a known inciting event. It just starts happening." Tr. 202. Dr. Schroeder's opinion regarding the onset of pain in asymptomatic rotator cuff injuries was repeated by Dr. Cagle. *See* Tr. 255. While chronic rotator cuff tears can become painful at some point, the transition is often caused by trauma or active use of the shoulder, which is not evident in this case. Further, as explained above, both the *Atanasoff* and *Cross* articles identify the vaccine injection as the likely cause for previously asymptomatic underlying shoulder pathology to become symptomatic, as a result of stimulating a prolonged inflammatory response. Dr. Schroeder and Dr. Cagle's opinions that petitioner's underlying asymptomatic rotator cuff tear suddenly became painful almost immediately after the vaccination without identifying any specific traumatic event or reason is less credible.

Therefore Dr. Schroeder's and Dr. Cagle's opinions in this case are given less weight, as there is preponderant evidence that petitioner's shoulder pain and dysfunction began with the intradermal flu vaccination and that his course was consistent with an immune-mediated

[18] Hesse, E. et al., *Shoulder Injury Related to Vaccine Administration (SIRVA): Petitioner claims to the National Vaccine Injury Compensation Program, 2010-2016*, 38 Vaccine 1076-1083 (2020). [Pet. Ex. 31].

[19] *FDA Licenses Sanofi Pasteur's New Influenza Vaccine Delivered by Intradermal Microinjection,* https://www.news.sanofi.us/press-releases?item=137080 (last accessed on May 23, 2022).

inflammatory response in and around his shoulder structures presenting as bursitis, tendonitis, pain and dysfunction.

As such, petitioner has demonstrated *Althen* prong two by a preponderance of evidence.

c. *Althen* prong three

Under *Althen* Prong Three, petitioner must establish a "medically acceptable temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has equated to the phrase, "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.,* 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one). *Id.* at 1352.

Petitioner argued that the onset of his shoulder pain and dysfunction occurred within 48 hours of receiving the intradermal flu vaccine on October 20, 2015. Pet. Post-Hearing Brief at 12. Dr. Srikumaran stated that onset of shoulder pain after vaccination "occurs within the first few days of vaccination." Tr. 109. Dr. Bodor agreed that onset of shoulder pain after vaccination typically starts within 48 hours. Tr. 146. Respondent's expert, Dr. Schroeder agreed that a shoulder injury occurs within 48 hours of vaccination because of the initiation of the innate immune response. Tr. 190. However, respondent argues that petitioner did not demonstrate that his shoulder pain began within 48 hours of the vaccination and that if he experienced pain, it was "localized pain related to the injection and unrelated to the rotator cuff tear that he was diagnosed with months after vaccination." Resp. Post-Hearing Brief at 15. In response to respondent's arguments, petitioner argued that he presented testimony from four corroborating witnesses confirming that the onset of his pain began within 48 hours, he called Dr. Sutton's office within two to three days Tr. 6 & 9, and the medical records consistently relate the onset of his pain to his flu shot on October 20, 2015. Pet. Reply at 4-5.

Consistent with the finding above regarding the onset of petitioner's right shoulder pain and dysfunction, petitioner has provided preponderant evidence to satisfy *Althen* prong three.

V. Conclusion

In accordance with the above, petitioner has established by preponderant evidence that he is entitled to compensation, demonstrating that the intradermal flu vaccine administered on October 20, 2015, was the cause-in-fact of his right shoulder pain and dysfunction. A separate damages order will be issued.

IT IS SO ORDERED.

s/Thomas L. Gowen
Thomas L. Gowen
Special Master